



Guide to German

Medtech Companies



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Guide to German Medtech Companies Vol. 9

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Editorial

Optimism is the root of success

The past year 2023 has not only brought us a new word, "polycrisis", but also a whole range of occurrences that have had a negative impact on the investment climate: wars, record temperatures, waves of migration, inflation, rising CO₂ emissions, a shortage of skilled labour, rail strikes, even more bureaucracy and much more unpleasant news. You can find out whether all of this has had an impact on the medical technology sector in Germany and Europe in our introduction from page 7 onwards. On the other hand, the megatrends that continue to drive the sector forward remain unchanged: scientific progress and the ageing of the population in many industrialised countries. The needs here are constantly growing and innovations are in demand. How companies develop therefore depends not only on the current investment climate, but also on individual entrepreneurial will and ability. And the German medical technology sector, which is characterised by many small and medium-sized companies, is doing well in this respect.

There are many so-called hidden champions in Germany that are also global players and are often family businesses. The stock market is more likely to feature medium-sized and larger medtech companies, which are included in a special index together with pharmaceutical and biotech stocks: in the DAXsector All Pharma + Healthcare (ISIN DE000A0SM7U2). And since the stock market is known to not only exaggerate, but also trade the future, it is worth taking a look at the share price performance. Between the end of 2022 and 2023, the index fell by around 10%. The polycrisis this year obviously took its toll, but this was apparently not due to the medtech stocks. Here are some major individual stocks in mid-December over 12 months: Siemens Healthineers +6%, Drägerwerk +8%, Fresenius +7%, Fresenius Medical Care +23%. Carl Zeiss Meditec, on the other hand, is down 31% – a difficult business situation in China is having an impact here.

It can be assumed that 2024 will not be an easy year either. We can only hope that at least some of the major crises around the world will move in a positive direction. Then confidence in the economy will rise again. This is essential, as optimism is the basic pre-condition for entrepreneurial action. "Business is 50% psychology" said former German Chancellor Ludwig Erhard more than half a century ago. With this in mind, we recommend that you, dear reader, take a look at the 9th Guide to German Medtech Companies and hope that you find some interesting ideas and information.



Andreas Mietzsch Publisher



Christian Böhm Sales & Marketing

Stuttgart/Nuremberg, Germany

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MedtecLIVE is much more than just an exhibition. It is the platform for the entire medical technology value chain, where the key industry leaders actively shape topics of significant interest.

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The European Medtech Space: Lots of light and some shadow

For a long time, the European medical technology market has taken pride in being one of the priority markets for approvals, second only to the USA. It was all but certain that the world's innovations would reach the European market, usually much sooner than elsewhere. Despite the many-voiced authorisation regulations in all the different European healthcare systems, the basic attitude was clear: health should have its price.

The scale of this healthcare market in Europe for medical technology alone remains impressive: the European medical technology market is estimated to be worth around €160bn in 2022. The five largest markets within Europe are Germany, France, the United Kingdom, Italy and Spain. Based on manufacturer prices, the European market for medical devices now accounts for 26.4% of the global market. It is the second largest market for medical devices after the USA (46.6 %).

COVID-19 affected the medical device industry in a number of ways. The postponement of elective surgeries in EU countries in 2020 led to the postponement of patient care in the orthopaedic and dental sectors. In 2022, the industry managed to overcome most of the disruptions caused by the pandemic and returned to pre-COVID-19 growth rates.

At the other end of the spectrum, sales of IVDs (e.g. PCR tests), patient support equipment (e.g. ventilators) and consumables (e.g. nasal cannulae, syringes, surgical gloves) skyrocketed during the pandemic, as these medical technologies were essential for the special care required by patients with severe COVID-19. But after the pandemic, in 2022, the IVD segment showed a sharp decline, returning to its customary level.

Global outreach – export is the engine

The European medical technology industry sells its products globally and is heavily dependent on exports, even if this differs from country to country. Ireland is the largest net exporter of medical technology in Europe, with a surplus of around €13bn and imports of goods worth just around €3bn. Germany ranks second in terms of exports, with a surplus of around €10bn and imports



worth around €22bn. Switzerland holds the third position with a surplus of approximately €7bn, surpassing the Netherlands, which has an export surplus of around €6 billion and imports medical technology products worth approximately €24.5bn. The UK, Spain and France, on the other hand, have a significant surplus in imports. Spain imports goods worth almost three times its medical technology exports. France imports around €4bn more than it exports, while the UK has an import surplus of around €2bn, similar to Italy. In the trade balance of European medical technology, Ireland, Germany, Switzerland, and the Netherlands contribute significantly with their combined export surplus of around €34 billion to Europe's total positive trade balance in medical devices with the rest of the world: This pan-european figure has seen a slight increase from €4.8 billion in 2021 to €5.2 billion in 2022.

But the rest of the world is not standing still. With the new authorisation rules for medical technology products (IVD/MDR), Europe has certainly done its bit for patient safety and this is not a small matter. However, the bureaucracy surrounding the rule change and lengthy coordination procedures between the Euro-

pean countries, including the disjointed implementation of the acceptance of new applications (of note, 'notified bodies' becoming active too late and in insufficient numbers), have sent a signal to the outside world: it is becoming more difficult in Europe, takes longer and costs more money.

US is the priority market

This perception of the European market is evident in a study conducted by the Boston Consulting Group at the end of 2022, which states that the "US replaces EU as priority market for [the] medtech industry".

Based on data from a survey of 104 senior executives, the Boston Consulting Group reports that the shift is being driven by the EU's "complex and unpredictable" medical device regulation, which came into force in mid-2021 and has made it more difficult to obtain a CE mark. According to Boston Consulting, some executives interviewed said: "MDR is killing innovation." The US has

Revenues 2022 €38.4bn

marketed products 500,000

F&E investment rate 9%

Export quota 67%

Employees 250,000

Companies 1,470

replaced the European Union as the priority market for medical device companies, with 89% of medtechs planning to prioritise FDA approval in the future.

The EU's decline in attractiveness comes at a time when the FDA has been courting the medtech industry. Two-thirds of respondents said the FDA has adapted well to the changes brought about by digital technology, while only 34% thought the same of the EU regulators. The FDA has "invested heavily to keep pace with digital trends" and the US has "emerged as the go-to market for global launches", a BCG report based on the survey data states.

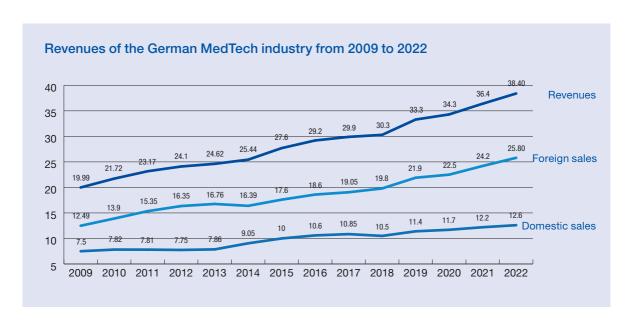
FDA pulls for innovation

In recent years, regulators on both sides of the Atlantic have changed their approach to medtech. The biggest changes have taken place in the EU, where MDR and the In Vitro Diagnostic Regulation (IVDR) are redefining what it takes to bring products to market in the region. At the same time, the FDA has set out to make the US the priority market for developers of novel devices.

In its most recent assessment, the FDA found that nearly two-thirds of novel technology device manufacturers plan to launch their products in the US first or in parallel with other major markets. The BCG report provides further evidence that the FDA is on track to achieve its set goal. The shift in focus from the EU to the US seems to have at least as much to do with what Europe has done to alienate the industry as what the FDA has done to woo it. For 23% of CE-marked companies, the EU has now fallen behind Japan and China on the list of priority markets, reflecting concerns about the impact of MDR and other factors.

Only 22% of respondents said the EU regulatory pathway for standard medical devices was predictable. The figure for the US was 62%. The FDA still has room for improvement, particularly with only 33% of respondents viewing its digital product pathway as predictable, but there was broad support for some of its key initiatives and a perception that it now offers a clearer path to market than the EU.

In the survey, 79% of respondents strongly agreed that the FDA is responding effectively to advances in medical



technology. According to the surveyed executives, when it comes to artificial intelligence and machine learning, US regulators also hold a competitive advantage.

Respondents praised the FDA's breakthrough device designation programme, with 88% saying the guidance is at least somewhat clear and 75% believing it will lead to faster patient access. More than half believe the programme supports more flexible trial design.

Concerns in Germany

Boston Consulting's 2022 survey is in line with BVMed's national survey for Germany, Europe's largest medtech country in terms of number of companies, employees and revenues.

According to the results of BVMed's autumn survey (October 2023), the medtech industry recorded an increase in turnover of 4.8% compared to the crisis year 2022, but this is offset by a sharp rise in costs of personnel, logistics, raw material and energy prices as well as the high costs of implementing the EU Medical Device Regulation. Germany now is under considerable pressure as a medical technology location. Small and medium-sized enterprises (SMEs), which make up 93% of the

industry and are drivers of innovation, are suffering the most. Investment in Germany is currently declining and research investments are increasingly being relocated abroad. According to the BVMed index, the climate for innovation is at an all-time low.

The BVMed Autumn Survey 2023 further states that the medical technology sector has recovered slightly after the crisis years of 2020 to 2022. 66% of the German medtech companies surveyed expect better sales results this year than in the previous year. This is a slightly better result than in the two previous years - but still falls short of the figures before the COVID-19 pandemic. 19% of the companies surveyed expect a decline in turnover, and for 12% of them, the expected decrease in sales will even reach the double-digit range. This shows that individual product areas in the medtech sector are developing very differently.

The weighted sales figures of the BVMed companies show an average increase in sales of 4.8% in the German market compared to the previous crisis year. With an increase of 6.4%, the expected global sales trend – where the exported goods are compiled – is significantly better than the domestic trend.

The increasing pressure on the industry is also having a greater impact on investments in Germany. More than a quarter of companies are reducing their investments. The situation is similar for research. One in five companies is reducing its research expenditure compared to the previous year.

The engine stutters ...

When it comes to the innovation climate, the BVMed Autumn Survey 2023 is raising the alarm: On a scale of 0 (very poor) to 10 (very good), companies rate the innovation climate for medical technology in Germany at an average of just 3.5. This is the lowest score since the index was compiled in 2012 and highlights the dramatic nature of the challenges facing the SME-dominated medtech sector in Germany. However, on a global scale, the numbers are impressive: Germany currently accounts for 12% of global medical technology exports, with 38.5% going to EU countries, 18.5% to the US, and 18.1% to Asia.

... but career prospects are excellent

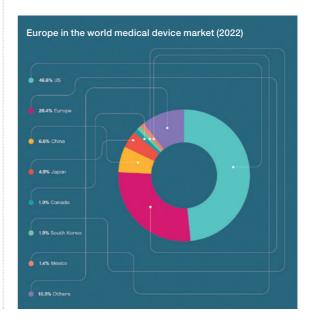
Despite the effects of the crisis and dramatically rising costs, the medical technology sector in Germany con-

tinues to create additional jobs. 31% of the companies that took part in the BVMed Autumn Survey 2023 are increasing the number of employees compared to the previous year, while 58% are keeping the number of jobs stable. The career prospects for specialists in the medtech sector remain excellent. The vast majority of companies (87%) believe that career prospects remain good or are improving.

Companies are primarily looking for engineers, computer scientists, data scientists and medical technicians, as well as skilled professionals in technical and commercial areas. The high value for data scientists shows that data-driven healthcare solutions are becoming increasingly important in the medtech industry.

The surge in Al-based solutions within medical technology and digital health is contributing significantly to the industry's current momentum and shaping its future trajectory. This, in turn, underscores the importance of upcoming European regulatory and standardisation initiatives.

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Our Cooperation Partners

New business through innovation in Germany

Germany Trade & Invest is the economic development agency of the Federal Republic of Germany. The company helps create and secure extra employment opportunities, strengthening Germany as a business location.

With more than 50 offices in Germany and abroad and its network of partners throughout the world, Germany Trade & Invest supports German companies setting up in foreign markets, promotes Germany as a business location and assists foreign companies setting up in Germany.

Medical technology-specific information and support includes:

- > Market research and industry reports
- > Financing and incentives options
- > Tax and legal information
- > Regulatory and reimbursement information
- > Matchmaking with industry and science
- > Site selection

Readers of the Guide to German Medtech companies are invited to contact GTAI should they need any support on their way to becoming established in Germany. This publication is of great value to companies looking to find out who's who in the German medical technology sector as well as seeking partners in Germany. GTAI's expert team is ready to assist your search for joint-research and contract manufacturing-project candidates across the country.

Advantage Germany

German medical technology is cutting edge. Hundreds of companies – nearly all of them small or medium-sized – produce medical technology innovations across the entire spectrum of products. Many specialise in very specific fields of applications or types of products.

While these companies may focus on niche markets, they are often world market leaders in their respective fields. Moreover, they continuously strive to improve their existing products: one in three products on the market has been developed within the last three years, with companies investing around nine percent of turnover in R&D.

Close cooperation between Germany's manufacturers and hospitals, universities and a plethora of research institutes helps the country maintain its internationally unparalleled competitive edge. R&D projects in the medical technology sector can also count on numerous types of financial support in the form of grants, interest-reduced loans, and special partnership programmes.

Germany is home to more than 30 medical technology cluster networks. Their goal is to achieve continuous innovation in R&D – as well as in manufacturing – by connecting companies, hospitals, universities, and other research institutions.

Dedicated cluster management teams help obtain funding for joint R&D projects, provide shared facilities, and organise educational training programmes for their members. A detailed overview of the cluster networks can be obtained from GTAI. Individual company requests are welcome.





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Health Made in Germany

Germany is one of the world's most important providers and exporters of healthcare products and services. The country's innovative medical products set international standards for quality, safety, and reliability. German manufacturers and service providers in all health and life sciences segments attract overseas customers and partners and deliver leadership in healthcare innovation.

HEALTH MADE IN GERMANY is the export initiative for the German healthcare industry. It supports international companies and organisations that are interested in establishing contact with potential German partners and suppliers. Set up by the German Federal Ministry for Economic Affairs and Climate Action (BMWK), the initiative bundles expert market intelligence for easy industry access. One of the initiative's main goals is to promote the German healthcare sector through international networking activities for the mutual benefit of international partners and German companies alike.

HEALTH MADE IN GERMANY does this by providing proactive support (including market and regulatory insight), introductory services, and networking platforms including trade events at home and abroad. The initiative serves four major industries active in the international medical market: pharmaceuticals, medical technology, medical biotechnology, and digital health care.

HEALTH MADE IN GERMANY also works closely with 16 major German industry associations and is part of the BMWK's MITTELSTAND GLOBAL umbrella program for small and medium-sized enterprises. The initiative is ideally placed to provide access to German healthcare market information and to help overseas businesses identify potential German partners.

The HEALTH MADE IN GERMANY initiative is implemented by Germany Trade & Invest, the economic development agency of the Federal Republic of Germany, on behalf of the BMWK.

For more information: www.health-made-in-germany.com

Our support for your business:

- > We publish market briefs, in-depth market studies and company directories of the German healthcare industry and its different sectors.
- Our calendar is regularly updated with the latest industry events in Germany and overseas.
- > We provide free access to 3,500+ German healthcare companies with our online database. Detailed company profiles and direct contact information help international businesses to identify potential suppliers and partners in Germany
- We take part in leading healthcare trade fairs all over the world, organise networking events, and enjoy ongoing dialogue and exchange with international health policymakers.
- Visit www.health-made-in-germany.com for more information about the German healthcare industry and all HEALTH MADE IN GERMANY activities.





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MEDICAL TECHNOLOGY in the German Industry Association SPECTARIS

SPECTARIS represents the interests of around 400 member companies in Germany, with four sector-specific associations in the areas of medical technology, optical technologies, and analytical, biological, laboratory and consumer optics. Through its political activities, public relations, and industry marketing, the association gives its members a voice, formulates new responsibilities, and opens up new markets. This ensures the international competitiveness of German industry in these sectors.



Lobbying | Industry Marketing – SPECTARIS promotes industry interests through our communication channels in politics, economics, science, and the media.

Market Research | Statistics – SPECTARIS creates substantial economic advantages through its national, European, and global market reviews and industry data.

Technology Consultation | Research Promotion – SPECTARIS' technological guidance guarantees access to monetary support programmes.

International Marketing | Promotion of Exports – SPECTARIS offers guidance on the global market and supports its members in securing international contacts.

In the medical technologies sector, SPECTARIS represents around 130 German capital goods and auxiliary aid companies who mostly produce high-tech products and have a pronounced export orientation. The member companies cover an extensive research and applications environment which includes medical products for diagnostic and surgery purposes, supply systems, and anesthesia and intensive care devices. The association also represents manufacturers of ophthalmic devices, large and small sterilisers, medical functional room equipment, respiratory home therapy, rehabilitation aids, and orthopedic technology.

The SPECTARIS trade association Medical Technology provides its members with support and information in various business areas and topics. In particular: financing, hygiene and processing, compliance, regulatory affairs, market access, research funding, and public affairs.





Chairman: Dr. Martin Leonhard, KARL STORZ SE & Co. KG; Vice-Deputy Speaker: Friedrich Schmitz, SCHMITZ medical GmbH

Global demand for German medical technology

- High significance of the European market: 37.4% of German medical technology exports go to countries within the European Union, a further 14.3% to the rest of Europe
- North America continues to be an important trade partner
- > Demand is growing in Asia, particularly from Japan
- > €38,39 billion turnover (2022), domestic turnover: €12,61 billion, overseas turnover: €25,78 billion
- ➤ European medical technology industry: >66,000 companies, €95 bn turnover, 600,000 employees



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Photonics, Analytical and Medical Technologies

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VDMA - Working Group Medical Technology Your network for success

The VDMA represents more than 3,600 German and European companies of the mechanical engineering industry. The industry stands for innovation, export orientation and medium-sized businesses. The companies employ around four million people in Europe, more than one million of them in Germany. Mechanical and plant engineering represents a European turnover volume of around 800 billion euros. With a net value added of around 270 billion euros, it contributes the highest share of the entire manufacturing sector to the European gross domestic product.

Production technology & components for medical products in focus

In the VDMA the fusion of machinery engineering and medical technology is manifold and offers tremendous potential for the future. The Working Group Medical Technology represents suppliers, manufacturers of production equipment, and all industry sectors active in the interdisciplinary field of medical technology within a joint platform. The Working Group is especially focused on pooling the heterogeneous interests of its members and providing an information platform for the companies, offering the opportunity to share and access relevant information.

With its huge network, the Working Group Medical Technology is in a position to recommend experts and to assist its members with fundamental issues. It offers market information for German and foreign markets, a comprehensive list of suppliers for the industry, activities for standardisation, and representation of political interest. Regular expert meetings and working groups provide information on various topics, including laws and regulations, production technology, components, and markets.

Another essential part of our activities is the substantive and organisational support of medical technology events through content or strategic partnerships and participation at national and international fairs: as one of the main supporters of the medical technology fair MedtecLIVE, through a joint stand at Compamed and

four German Pavilion in China (Medtec China), Ireland (Medical Technology Ireland), Singapur (Medical Manufacturing Asia), and in the USA (MD&M West).

Assistance with research and development

Medical technology is an innovative and dynamically growing sector. Around one third of its sales are generated with products that were launched on the market less than three years ago. In order to constantly renew and expand their product ranges, manufacturers and suppliers invest huge efforts in research and development. Close cooperation among everyone involved – from research and development to the supply sector and the manufacturers of medical products – is extremely important in making sure this investment pays off. To aid this cooperation, VDMA's Working Group Medical Technology provides its members comprehensive support in developing partnerships and collaborations. For example, research institutes gain the opportunity to present their developments for medical technology to interested companies at roadshows. In addition, we regularly bring doctors and hospitals together with engineers to discuss the future challenges facing medicine and to help to drive new developments forward.



Medical Technology



For more information: **Diethelm Carius** VDMA - Working Group Medical Technology Lyoner Str. 18 60528 Frankfurt am Main d.carius@vdw.de → www.vdma.org/medtec

Innovations netzwerk GESUNDHEIT: Innovations for Healthcare

The Health Innovation Network is a premier platform connecting innovators in industry, science, and medicine. As a dynamic driver of innovation and an inspiring source of expertise, our network serves as a reliable foundation for collaboration, knowledge-sharing, and networking. Topics like digitalisation, Artificial intelligence, robotics, regulatory affairs, sustainability, market access and care are online some of knowledge areas we are experts in.

The Network

- identifies trends, addresses these, and current topics along the entire value chain of the healthcare industry.
- > promotes cooperations.
- initiates, supports, and participates in projects.

Focus Areas and Projects

Within its main areas of focus, the organisation prioritises networking projects, a range of events, and personalised services. The 2023 merger of Forum MedTech Pharma e.V. with Bayern Innovativ particularly boosted digital expertise. Additionally, we strive to establish more cooperation within the innovation landscape, particularly with other technology sectors. Our goal is to facilitate cross-industry innovation and inspire collaborations.

The outcome is a robust market solution for the HEALTH ecosystem. Trends in the healthcare sector, like digitalisation, artificial intelligence, and robotics, can thus be thoroughly examined. The industry participants are given fresh ideas for processes, products, and subjects such as approval and reimbursement.

Become a Partner Now and Help Secure the Future's Medical Technology and Healthcare Together

As a partner in the Health Innovation Network, we provide you the chance to broaden your network and increase your visibility. Along with joining networking events like the virtual partner get-together or the yearly innovation network meeting, we'll highlight you as a partner and feature you in our newsletter. You also have the opportunity to submit expert articles. A personal contact with specialised subject knowledge will assist you with your questions, projects, and ideas. We promote a trusting exchange and individual networking amongst the partner community, facilitating connections with industry experts, collaborators, and potential project partners. Participation and active involvement in Circles of Experts or selected events are welcome opportunities to engage.





For more information:

Innovationsnetzwerk Gesundheit bei Bayern Innovativ GmbH

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→ www.bayern-innovativ.de/de/netzwerke-undthinknet/uebersicht-gesundheit/innovationsnetzwerkgesundheit

IVAM – The International Microtechnology **Business Network**

The IVAM Microtechnology Network unites people who are excited about key enabling technologies and the way these technologies shape our daily life and our future. As an international business network and technology marketing expert, IVAM creates trustful international connections between developers, manufacturers, and users of high-tech products. The focus is on small and medium-sized enterprises and their needs as well as on representation of their interests. IVAM was founded in 1995 and is one of the most experienced and efficient high-tech industry networks in Germany. "Climate crisis, pandemics, digitisation, collapse of the healthcare system, or demographic change: No matter what challenges await us in the future - microtechnology is part of the answer!"

(Dr Thomas Dietrich, CEO)

Microtechnology is the driver of ever-accelerating change

Microtechnology and related key enabling technologies like MEMS, nanotechnology, photonics, and advanced materials have significantly accelerated innovation in the late 20th and early 21st century. These technologies have affected, improved, or fundamentally changed many areas of society, industry, and the economy either by improving known products and processes or by triggering entirely new, previously unthought-of applications.

Many technologies that emerged in the 1990s, when IVAM started operating, have long since reached maturity. Consequently, technology suppliers today require support in marketing and finding customers. There is a growing need to access international markets. IVAM acts as a driver for innovation and offers well-founded orientation in the high-tech landscape and provides valuable know-how, e.g. through expert groups or studies on strategic questions concerning target markets, funding opportunities, application trends, or innovation management.



Business support worldwide

Medical technology has been the most profitable market for microtechnology suppliers in recent years. IVAM provides visibility to the technologies and products of its members: at international exhibitions and conferences as well as in virtual space via online meetings, online profiles, technical papers, blogs and podcasts, and other publications. Being found at the right time, in the right environment by the right customers: IVAM helps the sale of innovative high-tech products by supporting networking, contact building, and internationalisation, as well as supporting professionals on the career market.

IVAM has established joint trade fair areas at some of the most important medical supplier trade shows worldwide, such as COMPAMED (DE), MD&M West (US), Medical Manufacturing Asia, MMA, in Singapore, and China International Medical Equipment Fair, CMEF, (CN). In order to push business opportunities even further, IVAM arranges B2B meetings where innovative companies can exchange experience, discuss business ideas, and kick off joint projects.



For more information: **IVAM Microtechnology Network** Joseph-von-Fraunhofer-Str. 13 D-44227 Dortmund info@ivam.de → www.ivam.com

MedicalMountains – a strong network for a successful future

Baden-Württemberg is one of the leading locations in the medical technology sector. Its attractiveness reaches far beyond the country's borders. The district of Tuttlingen alone counts a concentration of more than 400 enterprises of the sector. For this reason, the region is also known as the "World Centre of Medical Technology". For many years, tradition and innovation have gone global from here.

Nonetheless the strongly regulated market and an intensely competitive environment raise permanent challenges for the sector. That is why a well-focused management of continuous advancement and an innovative network are an indispensable basis for long-term global success.

Success factor innovation – ideas that build bridges to the future

We are Medical Mountains: A cluster initiative for the medtech industry based in the heart of the World Centre of Medical Technology.

Shareholders of the MedicalMountains GmbH are the Schwarzwald-Baar-Heuberg Chamber of Commerce and Industry, the Tuttlingen District, the NMI Natural and Medical Sciences Institute at the University of Tübingen, the Surgical Mechanics Guild Baden-Württemberg, the Hahn Schickard Society for Applied Research, the Chamber of Crafts Constance and the city of Tuttlingen.

Our particular interest is to strengthen innovative capacity and long-term competitiveness, both for single companies as well as for the entire medical technology business cluster.

For this purpose we actively represent the interests of medtech enterprises on a political level, encourage innovation and technology transfer by directing work groups or R&D projects, organise training seminars and other informative events, and provide support for other service topics such as internationalisation or common marketing activities, amongst others.

MedicalMountains – more than just a loose affiliation of companies

The companies of the cluster consist of more than 90% small businesses and mid-sized companies, making the importance of the network even more crucial now than ever before. The medical sector is experiencing constant change and increasing competition worldwide. For companies of any size, collaboration and exchange with regional partners brings immense knowledge and a lead in technology – as well as enhancing the appreciation of the location for the region itself. MedicalMountains brings order to this natural, mutual structure. Future-oriented, prudent management is the basis for effective, constructive and farsighted developments in medical technology.

In collaboration with a growing network of industry, research institutions and government policies, the cluster initiative MedicalMountains actively represents the interests of medtech enterprises. The focus of the cluster initiative is to promote growth, strengthen competitive advantages, and increase the sector's international visibility even further. For this purpose MedicalMountains provides a platform for regular dialogue and technology transfer. It brings forward innovation by initiating directed project works, promotes qualification of specialised staff, and advises on subsidies or the opening up of new foreign markets. Our way of working is based on a close collaboration with the companies of our network.





For more information:
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→ www.medicalmountains.de

Cluster of excellence – Medical Valley EMN

The Medical Valley European Metropolitan Region Nuremberg (EMN) Association is an internationally leading innovation ecosystem in the area of healthcare management.

Highly specialized research institutions, international leaders, and many growing companies are active here. They cooperate closely with world-renowned health research institutions in order to jointly find solutions for the challenges of healthcare today and tomorrow.

This extraordinary concentration of players, combined with the international market and competitive position of individual players, plus the unique infrastructures and services, allows ideas to be turned into products, processes, and services more quickly.

The Medical Valley EMN currently has more than 260 members from business, science, healthcare, networks, and politics and has been contributing to the further development, coordination, and marketing of this ecosystem since 2007.

The nationally and internationally outstanding position of this economically strong region was additionally strengthened in January 2010 when it was designated as "Leading-Edge Cluster" for medical technology by the Federal Ministry of Education and Research (BMBF). In April 2017, Medical Valley, in cooperation with the Zollhof Tech Incubator and the Health Hackers, was named one of twelve national "Digital Hubs" by the Federal Ministry for Economic Affairs and Climate Action (BMWK) - the only one that focuses exclusively on health. Furthermore, Medical Valley EMN is a member of the consortium of EIT Health. With a budget of up to €80m p.a. for the next 7 to 15 years EIT Health is currently one of the biggest health research programmes worldwide.

Current projects include:

Team-X

Since January 2022, Medical Valley has been part of the "Trusted Ecosystem of Applied Medical Data eXchange (TEAM-X)" project. Within this framework, solutions are being researched and implemented with which future healthcare can overcome sectoral and domain-related boundaries.

The aim is to establish a protected and trustworthy digital data ecosystem based on the Gaia-X infrastructure for the development of data-driven business models, products and services as the basis for forward-looking healthcare.

EDIH DigiCare

Since June 2023, Medical Valley has been actively participating in the EDIH DigiCare project in collaboration with Bayern Innovativ Gesundheit to support the digital transformation in the healthcare sector. Medical Valley is positioning itself as a European digital innovation centre and acts as a central point of contact for start-ups, SMEs and public organizations to support them in overcoming digital challenges and sustainably increasing their competitiveness. Targeted services provide assistance and resources to optimally exploit the potential of digitalization in the healthcare sector.

TI-Modellregion Franken

In September 2023, Medical Valley, together with the consortium partners Bayern Innovativ Gesundheit and Monks - Ärzte im Netz, was awarded the contract by gematik GmbH to set up a telematicsinfrastructure model region in Franconia. The aim is to use TI applications and services that have already been rolled out and those planned for the future in day-to-day healthcare in order to subsequently use the experience and knowledge gained there to improve the applications and services on the one hand, and to demonstrate how the applications and services can make an important contribution in a wide variety of healthcare scenarios on the other.

Contact the cluster for more information:



Medical Valley EMN e.V Anna Goldsworthy

Phone: +49-9131-91617-48 / +49-159-06778755 E-mail: anna.goldsworthy@medical-valley-emn.de

microTEC Südwest – High-tech solutions for health

Our cluster

The leading-edge cluster microTEC Südwest e.V. is the competence and cooperation network for intelligent microsystems technology solutions for Europe and the contact for microsystems technology in Baden-Wuerttemberg. The cluster has set itself the task of expanding Baden-Wuerttemberg's internationally impressive position in the field of microsystems technology.

The cluster currently has about 110 members covering up the complete range from startups, to small and medium-sized enterprises, up to large enterprises, research institutions, and universities as well as further institutions.

Mission and topics

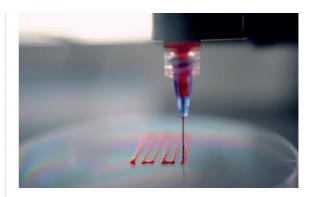
The mission of microTEC Südwest is the stimulation and promotion of cooperations in microsystems technology, utilising synergies and leading to economic dynamics. Our focus is on health (Smart Health) and production (Smart Production). Further activities address topics such as Smart Home, Smart Energy, and the Internet of Things.

In five different expert groups, microTEC Südwest bundles its expertise in order to jointly produce innovations in the field of microsystems technology.

Smart health

The expert group in vitro diagnostics aims to promote the transfer of technology and knowledge between research and industry in the field of in vitro diagnostics, including e.g. the application focus of decentralised testing/point-of-care diagnostics. Topics of the latest expert group meetings include e.g. Big Data for Next Generation Sequencing, telemedicine, and patient self-tests as well as sustainability.

The expert group micro medical technology focuses on the development of useful and safe products in the field of micro medical technology. It is thus committed to the research, development, approval, and reimbursement of these products, more specific diagnostic procedures, more effective therapies, and aids for rehabilitation



suitable for everyday use. Topics dealt with in the group include e.g. artificial intelligence at active implants, market trends, and minimally invasive diagnostics.

microTEC Südwest has been involved in different medical technology projects. An outstanding example is the project 3D Bio-Net, in which a 3D-bioprinter, suitable for multimaterial printing has been developed. Excellent results have been achieved in printing human tissues together with blood vessels. In addition, it was possible to print tailor-made and perfused microfluidic chips (for kidney & skin). This is an essential success in the development of persistent and vital organ models.



For more information:
microTEC Südwest e.V.
Emmy-Noether-Str. 2
79110 Freiburg im Breisgau, Germany
→ www.microtec-suedwest.de



Exhibition
Dedicated to the Design &
Manufacturing
of Medical Devices

2024 9.25-9.27

Shanghai, China

42,000+m²

Exhibition area

1,000+

Exhibitors

+000,08

Visits

Exhibit

Linc Cai

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- @ Linc.Cai@informa.com

Visit

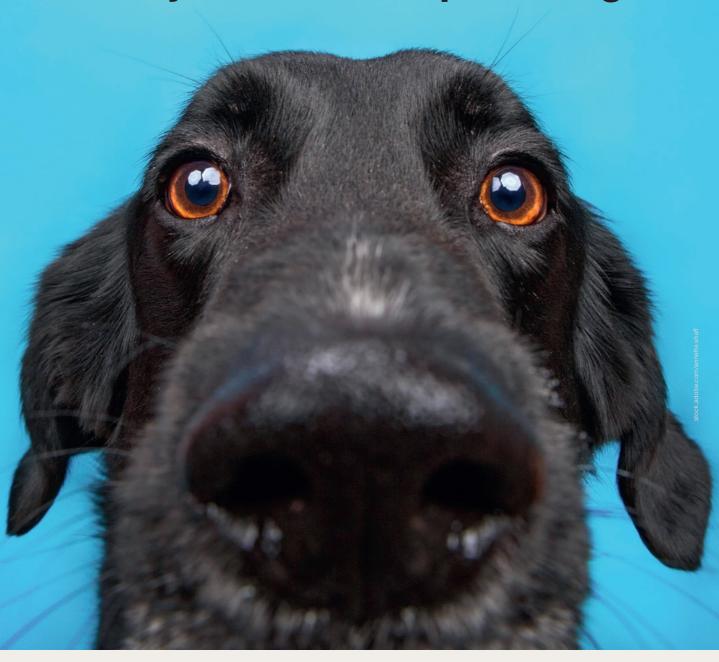
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informa markets

en.medtecchina.com

New job? Need help hunting?



eurobiotechjobs.net

Profiles of German Medtech Companies



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State > North-Rhine Westphalia

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Website > www.adapt-localization.com

Founded (year) > 1999







Translation Requirements under MDR, IVDR and Beyond

With the Medical Device Regulation (MDR) and the In Vitro Diagnostics Regulation (IVDR) in effect, the requirements regarding the information accompanying medical products have increased in the European Union. When evaluating the safety and usability of a medical device, regulators also focus on the user information that comes with it.

The EU regulations demand that it is "clearly comprehensible", and that it is provided in one or more "official Union language(s) determined by the Member State in which the device is made available to the user or patient." Also, several non-EU legislations in Europe have adopted these rules, and the regulations in Asia, the Americas or Africa have similar requirements. This usually means user information must be translated into the languages of all countries in which a device is sold.

The responsibility for the user information lies with the manufacturer, and ensuring it is correct across dozens of languages poses a considerable challenge. Notified Bodies and regulatory authorities are increasingly paying attention to which translation process a manufacturer has in place as it is regarded as critical; qualification of the translation supplier and their QMS plays a key role.

Compliance with the regulatory requirements for medical devices is best shown through ISO 13485 certification. In consequence, it makes things a lot easier for manufacturers working under MDR or IVDR if they can demonstrate the conformity of their supply chain through ISO 13485 certificates of their suppliers. That is why many medical device companies turn to ADAPT for assistance with their language management needs, from large global players to start-ups.

About ADAPT

Member of



EXPERTISE. ACCURACY. COMPLIANCE.

Premium language services for the medical and life science industries.



ADAPT Localization Services is a privately owned language service provider offering all linguistic and technical services required for a successful entry into international markets, including translation into all business languages, software localisation, desktop publishing, layout, graphics, multimedia, or source text review and optimisation. Headquartered in Germany, the company has been in the market since 1999 and maintains offices in Denmark, Spain and Sweden.

Quality Management & Certifications

As a leading company in medical and technical translation, quality, regulatory compliance and reliability are naturally core concepts in ADAPT's work. This is why our quality management system (QMS) is based on an ISO 14971/FMEA risk analysis and we are certified under

- ISO 13485 QMS for medical devices
- ISO 17100 translation services
- > ISO 18587 post-editing of machine translation

Specialisation & Technology

While humans and their expertise are at the heart of what we do, technology is a key factor at ADAPT. An extensive technical infrastructure is available, including state-of-the-art translation and localisation technology, numerous QA tools and an easy-to-use customer portal for secure data exchange.

ADAPT specialises in two areas:

- translations for the medical and life science industries
- > translations for related technology sectors

Within these fields, we provide our clients with the localisation of all materials they require - user interfaces, help systems, user manuals, training guides, multimedia presentations, marketing and promotional materials, instructions for use, or regulatory documents. After completion of a project, we can issue a certificate which confirms completeness and correctness of the translations.



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State > Hesse

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Website > https://eu.aspina-group.com/en/

Social Media > in

Number of Employees > 4400 worldwide

Founded (year) > 1918

Areas of Activity > Our comprehensive portfolio offers proven BLDC motors, stepper motors, blowers, and robotics components suitable for a wide range of applications in medical and laboratory technology. ASPINA drive solutions can be used in numerous medical application areas, for example ventilators, syringe pumps, micro & insulin pumps, or complex medical robotics and rehabilitation devices such as exoskeletons, centrifuges, and vacuum pumps.

Annual Turnover > €370m

Relevant R&D budget > 10% of annual turnover

Member of



Solutions in Motion

Through the design, manufacture, and supply of drive modules and systems, such as pumps, fans, and motors with reduction gears, we offer technical proposals for rapid issue resolution. We are experts in providing "movement" solutions. As industries evolve and customer demands shift, our mission remains clear: to present and craft products that are compact, lightweight, quiet, and yet powerful in performance.

Pioneering in ODM Services for the Medical Field

In addition to this, ASPINA offers ODM (Original Design Manufacturer) Services for the medical industry. An ODM manufactures products commissioned by other companies, which can be partly developed by the ODM itself and are sold under the name of the client. The desired concept is specified by the client and the ODM has the option of implementing the planning, design, and manufacture of the product. This approach allows partners of an ODM to offer branded products without having to operate their own factories. An example of a successful ODM project managed by ASPINA was the optimisation of an infusion pump for dialysis machines. Noise reduction and performance improvement were just a few of the benefits that could be offered to the partner and the patients.

Why ASPINA?

To successfully compete in the medical technology industry, innovation and the well-being of patients must be at the forefront. In this context, choosing the right partner in advance is crucial when designing new products for the market. Years of experience and a good understanding of the industry are indispensable requirements for designing and optimising products that deliver what they promise.















With over 104 years of experience, ASPINA has earned an excellent reputation in product development, as well as the status of a trusted partner for customers in the manufacture of technical equipment. From the customised idea to the implementation of production, ASPINA accompanies medical projects worldwide with an expert team of technicians and engineers to manifest customers' visions into reality. In addition to that, all major ISO accreditations, such as ISO9001, ISO13485, ISO14001, and IATF16949, are available.

Customers become Partners

Throughout our century of business activities, ASPINA has always thoughtfully considered the customers' needs and proposed solutions that exceeded their expectations. Thanks to this, many customers have chosen to become partners. This mindset, combined with a proactive stance, allows us to deliver greater added value. With over 2,000 registered customers and more than 9.000 drive system and motor models availabe. AS-PINA delivers individualised motor solutions all around the globe to improve the lives of partners and patients.

Clean air through patented compressor

For optimised usage of laboratory equipment for blood analysis or in oxygen concentrators, ASPINA offers a patented and specially designed compressor for a clean air flow. The ASPINA compressor offers a flow rate of 20 litres at a nominal pressure of 140 kPa. A built-in selfcooling fan eliminates the need for an external cooling fan, resulting in only an extremely small temperature rise during use.

By using 4 cylinders, the oil-less piston compressor is also particularly low in vibration & noise and features a compact, lightweight and maintenance-free design. A brushless 24 Volt DC motor with 200 rotations per minute and variable output guarantees a long service life with low power consumption at the same time.

BALLUFF

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State > Baden-Wuerttemberg

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Martin Kurz (Strategy Manager Life
Science, global)

Alicia Wüstner

(PR and Communications Manager)

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Website > balluff.com

Social Media > ¶ × in × □ □

Number of Employees > 3900

Founded (year) > 1921

Areas of Activity > Balluff is a leading supplier of high-

quality sensor, identification, and image processing solutions, including network technology and software for all automation requirements

Opening up new perspectives

Balluff is a leading supplier of high-quality sensor, identification, and image processing solutions, including network technology and software for all automation requirements. Family-run for more than 100 years, the company employs 3900 employees in 38 subsidiaries with distribution, production, and development sites worldwide, all working towards your success. Together with our branches in more than 61 countries, we guarantee the highest quality standards worldwide. This is how we empower you to always receive the best for your success.

We give our all to provide top services for innovative solutions that increase your competitive edge. Our consistent digital orientation is the driver of our progress, and our expertise is the success factor for our customers. We live our motto 'innovating automation': we are automation pacesetters, developers, and technological pioneers. In open interactions with associations, universities, and research facilities, and in close contact with our customers, we create new industry solutions for automation. As a future-oriented company, we not only focus on the traditional areas of automation, but are also dedicated to developing holistic applications for an increasingly digital and connected world.

Member of







Quality standards in assembly automation

Today, modern, application-optimised assembly machines are used for the precise and error-free assembly of medical technology components. With Balluff, you can successfully implement such intelligent production and smart manufacturing. Our sensors and interface components make a critical contribution to reliability of automated assembly processes.

Efficient processes in laboratory automation

When you require automated laboratory technology for transporting and processing samples in very confined spaces, Balluff provides you with optimal solutions for all fields of application in laboratory automation – with perfect interaction between optical and other sensor technology, miniaturised electronics, and precision mechanical components. Whether you want to detect and track objects or focus on efficient liquid handling, our sensors put you ahead - as important components of automated sample feeding and removal, as well as the dosing of sample material, or the analysis of liquids.



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State > Baden-Wuerttemberg

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Email > info@bantleon.de

Website > www.bantleon.de

Social Media > **f** in **⊠**

Number of Employees > Ca. 260

Founded (year) > 1918

Areas of Activity > We advise our customers on site and create individual concepts. Our offer covers the entire process chain of the metalworking industry: from machining the workpiece to cleaning and packaging.

Annual Turnover > ca. €132m

"QUALITY STARTS WITH ME!"

With this motto, we have been writing success stories for over 100 years. As a traditional top company in the region, we and our customers' processes are always in motion. And if no suitable lubricant can be found, then we custom-make it ourselves!

We are Hermann Bantleon GmbH. The lubricant specialist from Ulm. A medium-sized company with approx. 250 employees. We advise our customers on site and create individual concepts. We have specialised in offering our customers holistic product and service concepts consisting of cooling lubricants, cleaning, and corrosion protection, as well as maintenance and care of the media used.

It is precisely this holistic approach that demands close dialogue with customers, opens the way to innovations, and makes Bantleon a flexible and high-performance partner to industry. In the company's own accredited laboratory, the specialists develop and analyse products with and for the customer.

Transparency and traceability, as well as complete documentation, reflect the reliability and high quality awareness of the Ulm-based development, production, and service company.

Cooling lubricant concepts for the medical industry

Today, medical technology primarily uses materials that are difficult to machine. In addition to medical steel. magnesium, and ceramics, these also include titanium and cobalt alloys. The advantages are primarily to be seen in their safe biocompatibility and high corrosion resistance.

Today, Bantleon offers a wide range of technologies in the field of water-miscible cooling lubricants, which have also proven their worth in the medical sector. Cooling lubricants with high reserve alkalinity enable very long service lives, even under adverse operating conditions. These technologies have proven their worth, for exam-

Member of









©ulrich GmbH & Co. KG



ple, in the machining of titanium, steel, and cast iron. In the field of light and non-ferrous metals manufacturing, technologies with moderate pH have proven their worth. Our many years of experience with boron-free and amine-free product strategies have been transferred here from development into reliable modern cooling lubricant solutions. In addition to application-specific cooling lubricant properties such as flushing and lubricating effects, foaming, and residue behaviour, technological suitability for the available water quality and the materials to be machined must also be considered. Skin compatibility is confirmed in Bantleon product development through dermatological testing.

As a partner to the medical industry, Bantleon naturally also offers lubricant solutions in the field of cutting and grinding oils, as well as minimum-quantity cooling lubricants. High performance, low consumption, good cleanability in the downstream process as well as low workplace pollution are relevant for the users.

The use of low-mist and low-evaporation base oils with very high lubricity have proven their worth here. Synergistically acting additive systems matched to the materials are an important success factor in the respective process.

In addition, Bantleon's specialists work closely with our customers to develop optimised cleaning and packaging solutions. All according to the motto: "Through this collaboration, we jointly develop fluid technology and coordinate the processes, with monitoring by our specialist laboratory and fully traceable quality. This ensures the best possible solution and guarantees a satisfied customer."

Certification status:

ISO 9001 ISO 14001 **DIN EN ISO 21469** DIN EN ISO/IEC 17025

BAY0050FT

YOOme

your medical experts

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State > Hesse

Contact Person > Christian Becker, Sales Director

Y00me

Svenja Winkler, CEO BAYOOSOFT

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info@bayoosoft.com

Website > www.yoo.me

www.bayoosoft.com

Social Media > in

Number of Employees > 350+

Founded (year) > 2001

Areas of Activity > | Medical Software Engineering

| Medical Hardware Engineering

| Legal manufacturer as a service

| Healthcare

| Application

| Product Design

| Usability Design

| UX Design

| Management Software

YOOme Engineers your Medical Devices

Let's start your medical device journey – YOOme accompanies you from the idea to the end of the product life cycle. As a manufacturer, you have access to all services of the entire medical device journey via YOOme: Idea generation, conception and requirements engineering, medical hardware and software engineering, cybersecurity, validation and verification, design, usability & UX, market launch and maintenance. (www.yoo.me)

Your Benefits

Due to our corporate connection, we are a well-coordinated team and pursue one goal: To develop your medical device in a holistic and safe way. YOOme is your partner and authorised representative for your market launch in more than 50 countries, is MDSAP and ISO 13485 certified.

- User Interface Design: User research, target group and persona definition, UI design and prototyping
- Product Design & UX: Design analysis and strategy, corporate design, design development
- Product Development & Manufacturing: Security concepts, requirements analysis, system engineering, testing, hardware
- Medical Software: Digital health applications (DiGA), digital nursing applications (DiPA), mobile medical apps, quality management, cybersecurity, software verification
- Legal Manufacturer: CH-, UK-, EU-Rep, regulatory consulting, post-market-surveillance, vigilance

Revolutionising Healthcare Collaboration

Our platform, MedicalOne Connect, is revolutionising healthcare collaboration by seamlessly integrating and connecting all stakeholders. In compliance with GDPR, the DTx platform offers personalised treatment plans and tracks their progress.

Who we Are: YOOme x BAYOOSOFT

YOOme is the largest corporate network for the engineering of medical devices in Europe, consisting of five partners: BAYOOCARE (Legal Manufacturer),

Member of





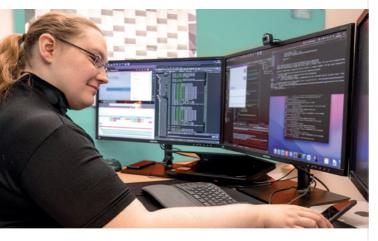






YOOME / BAYOOSOFT











BAYOOMED (Medical Software Engineering), Mechatronic (Product Development & Manufacturing), Puls Produktdesign (Product Design & UX) and UID (UX & UI Desian).

All YOOme partners are part of the 350 employees strong BAYOONET Group - as well as BAYOOSOFT, which has provided your Management Software Solutions for more than 22 years.

Focus on the Essentials and Increase **Productivity**

BAYOOSOFT reimagined the technical documentation, efficient and compliant: BAYOOSOFT Themis is your validated solution for documentation processes of medical devices and in vitro diagnostics - Digitise linked processes and sustainably reduce documentation efforts while minimising redundant data. (www. bayoosoft.com/themis)

How it Works

Processes are digitised and accelerated through the central management and linking of individual information units. Not only individual tasks, but entire process chains are thus optimised. As a result, the use of resources and error rates are far lower than with manual processing. At the same time, you reduce operational efforts and increase the acceptance of the developed files by your notified body.

On Top: Medical Data Protection

Since 2008, BAYOOSOFT Access Manager provides a transparent software solution for access and identity management for fileservers, SharePoint and Active Directory for manufacturers, pharma and hospitals. Especially for highly sensitive medical and patient data, it ensures security by monitoring access rights and an audit trail over all permission changes.

(www.accessmanager.net)

Free Trial and Online Presentation

We would be happy to introduce you to the performance of our products in a free online presentation - or get your trial here: www.bayoosoft.com.



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State > Hamburg

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(Market Manager Medical Device)

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Website > www.biesterfeld.com

Social Media > in

Number of Employees > >1000

Founded (year) > 1906

International distributor for the healthcare industry

Biesterfeld is one of the world's leading distribution and service companies in the field of plastics, rubber and specialty chemicals. Founded in 1906 in Hamburg, Germany, today the group has more than 1000 employees across 50 locations in Europe, North and South America, Asia and Africa and generates an annual revenue of 1.66 billion EUR. The fully family-owned company operates in the business divisions Biesterfeld Plastic, Biesterfeld Spezialchemie and Biesterfeld Performance Rubber.

Everything from a single source

Due to extensive experience and long-standing partnerships with leading international suppliers, Biesterfeld Spezialchemie and Biesterfeld Plastic are well positioned in the healthcare industry, distinguished by:

- team of experts, technical engineers, product and marketing managers with extensive market knowledge worldwide
- decentralized sales network with local contact persons, serving more than 20.000 customers in over 120 countries
- active market development combined with high innovation capacities
- application-based technical advice on product development and process optimization
- independent material recommendations
- diverse product portfolio with customized commercial and logistical solutions
- application laboratories offering formulation development, product test and in-house training

Competence in Quality & Regulatory

Both business divisions, Biesterfeld Plastic & Biesterfeld Spezialchemie, possess numerous certifications and quality seals, e.g. Operation Clean Sweep, ISO 9001:2015, ISCC+. Furthermore, Biesterfeld Spezialchemie operates a regularly audited GDP-compliant pan-European quality management network which is centrally managed from the Hamburg-based headquarter and involves the central



Wearable medical devices are built of several unique layers



- Delrin® Moving Parts Solutions Celanese™ Crastin® Housing Solutions
- Dvmax® **Electronics Encapsulation**
- Dymax® Needle-to-Hub Bonding
- Dymax® Edgebond
- Dymax® Battery Reinforcement
- Dymax® Wire and Flex Tacking
- Dymax® Assembly Bonding
- DuPont™ Liveo™ Silicone Skin-Adhesives

warehouse and logistics. Together with our extensive knowledge of industry-specific regulations we are able to provide added value regarding Quality & Regulatory topics for our customers and partners.

Your partner for medical device development

The global market for wearable medical devices is expected to grow rapidly in the next years due to a number of factors, e.g. increasing geriatric population, alarming prevalence of chronic diseases and growing fitness and health awareness.

Not least due to the pandemic, on-body medical devices are seeing rapid consumer adaptation. Self-optimization, data retrieval and outpatient care are deeply rooted in the growing desire to track our health. In order to get a share of this highly competitive market it is of great importance to set standards already in the process of selecting the best raw materials.

At this early stage of product development, Biesterfeld is your competent partner guiding you through every step of the process.

Depending on your requirements, we offer a broad and innovative product portfolio:

Crastin® PBT for housing parts

- Delrin® POM-Homo for moving parts
- > DuPont™ Liveo™ silicone skin adhesives for device attachment to the skin

Celanese[™]

Dymax[®] MD UV-curable adhesives for assembly bonding, electronics encapsulation

and edge bonding



Name > Bürkert Fluid Control Systems

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State > Baden-Wuerttemberg

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Email > info@burkert.com

Website > www.burkert.com

Social Media → 🖪 Xin 🗸 🗅 🖾

Number of Employees > More than 3,500

Founded (year) > 1946

Areas of Activity > | Measuring, control and regulating systems for liquids and gases

> | Components, customised systems, services and automation solutions

Lab & analytical as well as medical

| Solenoid valves, analytical valves, proportional valves and sensors

Annual Turnover > €719,7m (2022)

We make ideas flow

Bürkert Fluid Control Systems is one of the world's leading manufacturers of measuring, control and regulating systems for liquids and gases. Bürkert solutions are used in a wide range of industries and applications - ranging from breweries and labs to medical, bioengineering and aerospace technology. With a portfolio of more than 30,000 products, Bürkert is the only supplier to offer all fluid control system components, from solenoid valves to process and analytical valves, from pneumatic actuators to sensors. Bürkert continuously develops customised solutions and innovative products at its five Systemhaus locations in Germany, China, and the USA, and in four research centres.

In vitro diagnostic: Precision, automation and increased throughput

The precision and accuracy of the analyses determine the diagnosis. At the same time, the speed and the space required for the device in the laboratory are essential for in vitro diagnostics due to the rapidly increasing need for tests.

Our systems are not just ideal for your applications for reasons of speed and compactness. Our extensive portfolio of media-separated valves has established itself as the benchmark in IVD fluidics over the past few decades. This makes Bürkert an experienced full-service provider in all processes of clinical diagnostics. In addition, we provide you with the documentation for our products and systems. Depending on the applicable medical regulations and guidelines, these can make it easier for you to apply for any approvals for your entire device.

More Information:

www.burkert.com/in-vitro-diagnostics





Ventilators: Reliable, precise gas control

If vital bodily functions, such as breathing, no longer work independently, patients are instructed to use ventilators. It can only be guaranteed that the patient is being supplied with sufficient oxygen when the device controls the supply of air and oxygen exactly. Adjustable gas concentrations are just as important as correct volume flow rates and pressure.

Collaboration with Bürkert will enable you to concentrate on user-friendliness and ventilation modes as a manufacturer. Our experts will support you with individual fluid technology in compact designs, solutions for mixing and controlling gases. Our experts rely on tried-andtested, individually combinable standard components in compact designs for this work. By doing this, we then reduce development costs for your requirement profile. We also contribute our expertise in digital data acquisition and processing.

More Information: www.burkert.com/respiratory

Dialysis: Highly integrated and cost-effective system solutions

As the prevalence of chronic kidney disease increases globally, so do the demands on modern dialysis devices: Patients expect functional reliability and comfort, the healthcare system increases cost pressures, manufacturers of dialysis devices strive to take advantage of market growth opportunities.

Bürkert is the ideal partner for the challenges involved in dialysis, thanks to its industry-specific portfolio covering all types of fluid handling (valves, sensors, pumps, controllers).

We offer you proven, innovative fluid systems that are also highly integrated and cost-effective - including multifunctional, compact application solutions to help you optimise and monitor processes, save space and increase functional reliability and operational safety.

More Information: www.burkert.com/dialysis



Name > Cicor Group

Address/P.O. Box > Gebenloostrasse 15
Postal Code/City > 9552 Bronschhofen

Country > Switzerland
Telephone > +41-71-91373-00

Email > info@cicor.com

Website > www.cicor.com

Social Media > in 🖸

Number of Employees > 2,500 worldwide

Founded (year) > 1966

Areas of Activity > | Engineering Services

| Electronic Manufacturing Services

| Precision Plastics

| Hybrid Circuits

| Printed Circuit Boards

| Printed Electronics

Annual Turnover > CHF 313m (2022)

Cicor Group – your technology partner

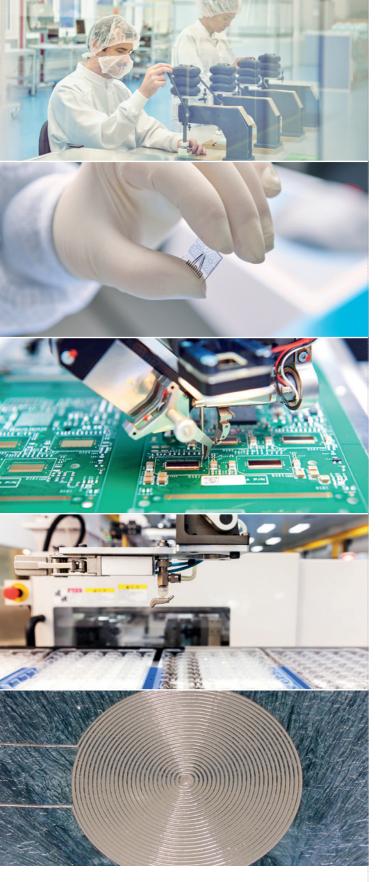
The Cicor Group is a globally active provider of full-cycle electronic solutions from research and development to manufacturing and supply chain management. Cicor's approximately 2,500 employees at 15 locations are serving leaders from the medical, industrial and aerospace & defence industries. Cicor creates value to its customers through the combination of customer-specific development solutions, high-tech components, as well as electronic device manufacturing.

Customised solutions

Cicor works together with customers to develop innovative products and offers solutions that meet the needs of the market, reflect the latest trends, and convince through their application. Cicor's broad portfolio of innovative technologies, services, and global production capacities offers the right solution for even the most demanding requirements, such as high-tech and high-reliability applications. Thanks to a focus on consistent quality and maximum traceability, rapid prototyping, flexible choice of materials, miniaturisation, as well as development and assembly services, Cicor is able to meet the requirements for medical devices by using new ideas and cutting-edge solutions. Cicor supports its customers starting in the planning stage and provides the best outsourcing solution, tailored to the specific needs. Cicor is your technology partner over the entire product lifecycle, from product development through series production to after-sales service.

One-stop shop for electronics and precision plastics solutions

Cicor is an EMS provider with a broad range of production capabilities in printed circuit board assembly, microelectronic assembly, cable assembly and box building, as well as tool design and fabrication and plastic injection molding. Cicor offers complete outsourcing solutions for the development and manufacturing of complete electronic devices and systems. As a company with global operations in Switzerland, Germany, the UK, Romania, Singapore, Vietnam, Indonesia, China, and Tunisia, Cicor employs its synergies to offer solutions based on long-term know-how.



Innovative power through technological expertise

As a leading manufacturer of sophisticated microelectronics and high-quality substrates, Cicor is able to provide a broad range of products and services of the highest standards. In the area of microelectronics, Cicor offers state-of-the-art assembly and packaging technologies under clean room conditions. In the field of substrate manufacturing, Cicor is characterised by the production of highly complex rigid, rigid-flexible, and flexible printed circuit boards and substrates using thin-and thick-film technology. Cicor works closely with its customers to develop and manufacture sophisticated products, ranging from prototypes to large-scale serial production. Cicor also offers a high degree of process stability, consistent top-quality, and absolute delivery reliability.

Sophisticated implants

Cicor manufactures complex circuits of various materials and realises ultrafine structures, which can be less than 0.02 mm thick despite having a high functional density. Using CiP (chip in polymer/plastic) technology, the overall thickness of chip packages can be reduced to between 60 and 100 µm. State-of-the-art technology makes it possible to manufacture multilayer circuits from biocompatible materials or stretchable components in conjunction with multilayer technology on flexible substrates.

Printed electronics

The unique printing technology used, enables a wide range of conductive, non-conductive and biocompatible materials to be printed on a wide range of substrates and forms. In addition, new opportunities exist for interconnect technologies that can lead to performance improvements and cost optimization.

The integration of the circuits into three-dimensional surfaces often eliminates the need to use an additional substrate. Compared to the methods used today to produce such three-dimensional circuit carriers, the technology chosen by Cicor offers a significantly wider variety of printed and printable materials. Devices for medical, aerospace and IoT applications can be significantly reduced in size by using this technology.



Name > CONZE Informatik GmbH

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Email > info@conze.com

Website > www.conze.com

Social Media > f × in × ☑

Number of Employees > 40

Founded (year) > 2009

Areas of Activity > | Cloud Services / Transformation

| Desktop Software

| Embedded Device Software

| Artificial Intelligence

| Mobile Apps

| User Experience Design

| Usability Engineering

| User Interface Design / Visual Design

| Facelift / Redesign

| Styleguide

| Tech-Scouting

| Design Thinking & Management

| Prototyping

| Code & GUI Reviews

I C++, C#, .NET, WIN UI, MFC, WPF, UWP, Qt, ASP.NET Core, Angular,

React Native, Flutter

externai Collaborations

External > | University of Siegen

Collaborations | Brancheninitiative Gesundheitswirtschaft Südwestfalen e.V.

| Forum MedTech Pharma e.V.

| German UPA e.V.

| Bundesverband IT-Mittelstand e.V.

| VDE Verband der Elektrotechnik Elektronik Informationstechnik e.V.

Member of











Healthcare, your perfection. Software, our passion.

CONZE Informatik GmbH is a specialist in the development of user interfaces (GUI/HMI) of advanced devices and software systems for customers from medical technology and healthcare. To ensure a smooth placing of the medical device on the market, CONZE is certified according to DIN EN ISO 13485 and DIN EN ISO 9001 and observes relevant norms and standards such as IEC 62304 and IEC 62366. In this way, the service provider guarantees the high quality and safety standards in medical technology.

Competence from the digital workbench

As an established remote development team, the company expands the workforce of its customers. From development to project management, CONZE acts as a digital workbench for HMI departments, creating UI/UX experiences and visual designs as the graphical user interface of the customer software. This also includes the designing of icons or the writing of style guides. CONZE's developers implement all the necessary features and functions to ensure that the user interface runs smoothly and robustly in critical environments.

The transparent cost and performance-optimised project management keeps customers up to date on the status quo, budget, and resources at all times in the project and is available with active solution proposals. It identifies bottlenecks or even risks at the earliest stage in order to react flexibly to changing requirements and actively present an appropriate solution. Thus, the team manages the daily balancing act between process-critical solutions in medical technology, user-friendly product design, and compliance with legal regulations. This allows the consistent development of international, market-ready software solutions of high quality according to the highest standards.



New web and mobile app development framework for faster time to market

CONZE has expanded its portfolio with its own framework for Digital Health Applications (DiGA/DiPA). Thanks to very low initial efforts, Minimal Viable Products (MVP) can be quickly generated, and can already be tested for market acceptance before lengthy development cycles are started. Decisions on applications, migrations, or new developments can thus be made on the basis of a quickly available and calculable feasibility. The framework has already been tested in the medical environment with the development of a digital blood pressure diary, as well as the process digitisation for the recording of electronic signatures.

Medical quality management and safety

In order to guarantee and verify the high quality and safety standards of medical technology according to MDA/IVDR/FDA, CONZE's quality management is certified by TÜV Hessen (DIN EN ISO 13485, Medical devices - Quality management systems; Requirements for regulatory purposes) and TÜV Rheinland (DIN EN ISO 9001). CONZE complies with IEC 62304 (Medical device software - Software lifecycle processes), DIN EN ISO 14971 (Medical devices - Application of risk management to medical devices), and IEC 62366-1 (Application of usability engineering to medical devices).

The innovative strength of tomorrow

As a cooperation partner of the University of Siegen, CONZE is involved in the research of the Chairs of Life Sciences, Medical Computer Science, and Human Computer Interaction. In this way, the international character of the research and the flow of knowledge are expanded in the long term.

Get in touch!

Benefit from experience and knowledge in the field of User Interface Engineering. Talk to the CONZE experts about your current or future software project.



Name > CSA Group Bayern GmbH

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Postal Code/City > 94447 Plattling

State > Bavaria

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Email > Marcel.Laven@csagroup.org

Website > www.csagroup.org

Social Media > **f x** in **□**

Number of Employees > ca. 2,000 worldwide

Founded (year) > 1919

Areas of Activity > | Product Testing Inspection and

Certification

| Standards Development

| Global Market Access

About CSA Group

CSA Group is a global organisation dedicated to safety, social good, and sustainability. We are a leader in standards development and in the testing, inspection, and certification of products around the world including Canada, the U.S., Europe, and Asia.

Our areas of focus for testing, inspection, and certification services are the healthcare, industrial, home, and commercial industries.

Testing & certification services for the healthcare industry

Accredited as a National Certification Body (NCB) through the IECEE CB scheme and recognised by Authorities Having Jurisdiction (AHJ), we offer leading healthcare systems conformity assessment services, as well as testing and certification to leading international standards, such as IEC 60601-1, including the collateral standards and the applicable particular standards, and IEC 61010-1 with the applicable particular standards.

Our technical knowledge of medical electrical equipment and systems, and laboratory & measurement equipment, along with our knowledge of the compliance requirements in major world markets, work together to help you remove barriers to global market access.

CSA Group offers a comprehensive safety and compliance testing service offering. We offer testing and risk management evaluations throughout the product lifecycle and can offer tests for:

- > Electrical safety
- Electromagnetic compatibility (EMC)
- Cybersecurity
- Interoperability
- Wireless applications
- Global market access
- Coexistence testing services





Medical electrical equipment and systems

Medical electrical equipment and systems offer invaluable benefits but can also present great health and privacy risks through flawed design or malfunction. The experts at CSA Group can help you identify and resolve risks so you can safely and confidently go to market. We provide standards, testing, and certification for a wide array of medical electrical equipment and systems

- > Patient Monitoring
- Diagnostic Imaging
- Medical Robotic etc.

for:

and products such as:

- > CT Scanners
- Incubators etc.

Laboratory & measurement

Take advantage of CSA Group's healthcare industry expertise to prepare your laboratory, control, and measurement equipment for the global market with fast and reliable services.

Laboratory and measurement equipment must meet demanding standards for precision and reliability. Trust CSA Group experts to help you identify and resolve flaws so you can confidently go to market.

We provide testing, certification, and standards solutions for a wide range of laboratory, control, and measurement equipment, such as:

- Centrifuges
- Autoclaves
- Mass Spectrometers
- In-vitro Diagnostic Equipment
- Multimeters



Name > DC Advisory

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Country > Germany

Telephone > +49-69-972-0040

Email > Enquiries@dcadvisory.com

Website > https://www.dcadvisory.com/

Social Media > X in ☑

Number of Employees > 700

Areas of Activity > Delivering tailored and impactful solutions, DC Advisory leverages product experts across multiple markets - combining M&A, debt, coverage and specific capital raising expertise.

DC Advisory is an international investment bank committed to making a difference. As part of an established global business, we offer access to over 700 professionals in 23 locations throughout Asia. Europe and the US. Across eleven industry-focused teams, we offer tailored, independent advice on M&A, debt raisings and restructurings, private capital and access to unrivalled Asia investment knowledge.

DC Advisory is owned by Daiwa Securities Group Inc., which is one of Japan's leading financial institutions operating since 1902.

Global Healthcare Team

Our global healthcare team has extensive experience across a broad range of healthcare sub-sectors, with a track record in delivering results for clients, anywhere in the world.

Key sub-sectors include:

- Medtech & life sciences
- **>** Pharma
- > Healthcare IT & supply chain
- Care & services

Globally, DC Advisory has completed c. 150 healthcare transactions since 2010. Selected notable transactions include advising:

- Altor on the acquisition of VTU Group
- Yocera on the acquisition of H.C. Stark Ceramics
- > UCB on the sale of Apontis Pharma (fka Innere Medizin) to Paragon
- > Sanofi on the sale of an OTC portfolio in Germany and Austria to Angelini Pharma
- > Ardian on the acquisition financing of imes-icore
- > Berchtold on its sale to Stryker
- Sysmex on the acquisitions of Partec and Inostics

Key contacts:

Dr Wolfgang Kazmierowski Managing Director Germany, Frankfurt Wolfgang.Kazmierowski@dcadvisory.com

DC ADVISORY









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State > Baden-Wuerttemberg

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(Key Acconut Manager - Healthcare & Laboratory at Dunkermotoren)

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Social Media > in 🗅 🖸

Number of Employees > 1300

Founded (year) > 1950

Areas of Activity > Drive technology for healthcare

equipment and devices such as:

| X-ray, CT or MRI machines

| dialysis pumps

| operating tables

I diagnosticy equipment

| rehabilitation equipment

cryotherapy

Benefit from More than Seven Decades of Experience in Drive Technology:

Since 1950, Dunkermotoren has been developing and producing innovative, flexible, and high-quality motor solutions made in Germany. The portfolio includes brushless and brushed DC motors, linear systems, and AC motors from 1 to 5,000 W output power. Within a modular system, those can be combined with gearboxes, encoders, brakes and integrated or external electronics, to form a complete motor unit. All components are being developed, produced, and tested in-house. By launching its own Industrial IoT brand nexofox in 2021, Dunkermotoren crossed the border from a drive technology manufacturer to a full-service provider. With nexofox, Dunkermotoren motor solutions and automation systems of its subsidiary EGS Automation can be connected to the cloud and make use of features such as individual programming, condition monitoring and predictive maintenance, all by using own or existing ecosystems.

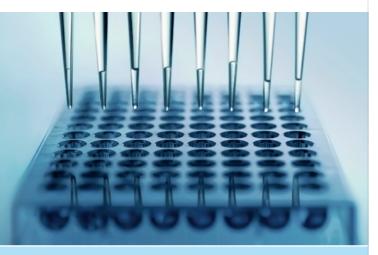
Headquartered in Bonndorf in the Black Forest, Dunkermotoren offers an impressive portfolio with global reach and local production thanks to more than 1,300 employees around the world.

Driving the World in All its Facets:

an automated and connected world.

Dunkermotoren is providing motor solutions for various future-oriented and technology-driven industries such as intralogistics and robotics, machinery and plant engineering, packaging automation, agricultural and (auto-) motive technology, as well as the healthcare market. This broad area of application allows Dunkermotoren to transfer the knowledge, technology, and experience gained in one segment into other application areas to develop innovative, state-of-the-art drive solutions for

DUNKERMOTOREN







Motor Solutions for a Healthy Future

Whether CT scan or X-Ray machines, laboratory equipment, dialysis pumps, operating tables, or rehabilitation equipment - a smooth, precise, quiet, and reliable operation of medical devices is crucial for the daily operation of healthcare companies and for adequate medical care. Mobile applications can provide additional relief for the hospital staff and offer a high degree of comfort for the patients. Since failures of this equipment can delay vital treatments, possible malfunctions must be predicted with reliability or avoided entirely. Dunkermotoren brushless DC motors are maintenance-free, precise and can be individually programmed based on applicationspecific requirements. With nexofox, devices using smart Dunkermotoren solutions can be connected and monitored, thus contributing to a networked medical technology infrastructure using features such as remote control and predictive maintenance (Internet of Medical Things - IoMT).



Name > EPflex Feinwerktechnik GmbH

Address/P.O. Box > Im Schwöllbogen 24
Postal Code/City > 72581 Dettingen

State > Baden-Wuerttemberg

Contact Person > Georg Uihlein

Telephone > +49-7123-9784-0

Fax > +49-7123-9784-22

Website > www.epflex.com

Social Media > 🗗 🗸 🖸 in

Number of Employees > 400

Founded (year) > 1994

Areas of Activity > Components for minimally invasive medicine

Annual Turnover > €40m

Vision & Mission

With our innovative medical devices, we push the boundaries of minimally invasive surgery every day and set new standards for interventions. For patients, this means shorter procedures, less pain and faster recovery.

EPflex - better ideas, better health

EPflex is one of the pioneers in the development and manufacture of components for minimally invasive medicine. Next to Guidewires and Stones Retrieval Devices, which can be produced in various designs and modifications, EPflex is dedicated to being a competent development partner that supports its customers from the first idea right up to series production and Regulatory Affairs.

With a number of different manufacturing competencies and its own tool-shop, EPflex is capable of producing a wide range of different product types precisely in line with customer specification. Initial prototypes can be rapidly and flexibly manufactured in the just recently built Technology Center, which allows the customer to witness the transformation of their ideas into reality firsthand.

Quality right from the start

As a family-owned business in second generation, EPflex is aware of current requirements when it comes to high-quality services.

This applies to all the products as well as the support in assisting the customer regarding regulatory questions and technical documentation.

EPflex is DIN EN ISO 13485 certified and will be receiving its MDR CE submission for several products and applications in 2024.

Guidewires

The EPflex Guidewires are high-tech instruments, developed and manufactured on the basis of years of experience and outstanding expertise. The company can offer a wide range of Stainless Steel and Nitinol Guidewires for a variety of applications – tailored to the customer specification.



FPFLEX FEINWERKTECHNIK



Nitinol Stone Retrieval Devices

EPflex Stone Retrieval Devices are manufactured with the highest precision and guarantee the best quality when using Nitinol for Urological and Gastroenterological procedures. The company can offer Baskets with or without tip as well as open Graspers which perfectly facilitate the gripping and releasing of the stone.

Snares

FPflex snares are made of Nitinol to ensure kink-resistance and exceptional flexibility. For enhanced radiopacity, a gold-plated Snare tip version is also available.

Stylets

EPflex Stylets are individually manufactured according to customer requirements. Whether the mandrels are coated, ground, sandblasted or specifically tailored, the company can rely on a wide Stainless Steel and Nitinol stock and several manufacturing competencies.

Turned and Milled Products

The EPflex tool-shop is specialised in the production of very small turned or milled parts that can be used as a manufacturing tool or as a component for a finished medical device.

Manufacturing competencies

- Coating
- Electrochemical Marking
- > Electropolishing
- Gluing
- Grinding
- Laser Marking
- Sandblasting
- Shrinking
- Turning & Milling
- Welding (Laser & Plasma)
- Wire Forming

Medical Areas

- Urology
-) Gastroenterology
- Vascular Surgery (Cardiology or Peripheral)



Name > ETO GRUPPE

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Postal Code/City > 78333 Stockach

State > Baden-Wuerttemberg

Contact Person > Bernd Hardy

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Email > info@etogruppe.com

Website > www.etogruppe.com

Social Media > f × in √ □ 🖸

Number of Employees > 2,500 worldwide

Founded (year) > 1948

Areas of Activity > | Medical and care technology

| Smart materials

| Passenger cars and commercial vehicles

| Hydrogen technology and e-vehicles

| Connected and assisted driving

| Transport infrastructure technology

| Logistics

| Industry

| Environmental and agricultural technology

I IoT, web3 software and applications

Annual Turnover > €478m Relevant R&D budget > €34m

External > Numerous projects with selected

Collaborations customers and start-ups, different
universities, and research institutes

In Medtech for over 30 Years

With 12 locations and over 2,500 employees worldwide, the ETO GRUPPE develops and manufactures electromagnetic drive components, sensors, electronics and software for use in devices, machines, cars and trucks. For over 30 years, ETO GRUPPE has also stood for reliable and durable medical technology components. In addition, hydrogen technology, electric vehicles, autonomous and assisted driving and traffic infrastructure technology are key topics for ETO. The company also offers innovative applications in the fields of industry, environmental and agricultural technology, care technology and Web3 applications.

Innovative Start-up Mentality

Even though the ETO GRUPPE has been on the market for more than 75 years, our company has always maintained a start-up mentality. Today, we route new ideas through the "Inno Funnel", an internal process that was created to tap into the swarm intelligence of the employees. As a foundation, ETO is able to invest around six percent of its annual revenue in R&D alone. This results in a strong capacity for innovation, reflected in a high number of patents.

ETO HUMEDIC – Medical Technology from ETO

For dialysis machines, the ETO GRUPPE offers solenoid valves with media separation that have been validated to last for 50 million switching cycles. We also provide durable hose pinch valves with an integrated fail-safe mode that disconnects a hose connection to the patient or laboratory equipment in the event of a fault or power failure.



ETO GRUPPE

For dental drilling machines, ETO supplies a pneumatic proportional valve for precise and infinitely variable drill speed control. For the hydraulic adjustment of operating tables, dental chairs and other equipment, ETO supplies hydraulic valves with proportional characteristics for extra smooth operation.

A compact, fast-switching vacuum valve from ETO ensures safe and fast fixation of a skin sensor for measuring vital signs during EEG and ECG measurements. Air pressure sensors with strict media separation are used in dialysis and respiratory devices for continuous blood pressure measurement. Thanks to compact dimensions of only 19 mm x 19 mm, integration into circuit boards is seamlessly possible.

First to Market with Smart Materials

For the safe handling or manipulation of sensitive samples and medtech components, ETO supplies a miniature gripper with innovative sensor technology. Its gripping function is based on a smart material and ensures fail-safe mode in the event of a power failure. The smart material called MAGNETOSHAPE® is a ferromagnetic shape memory material that only the ETO GRUPPE will be able to provide. A special feature of the gripper is the gripping force, which can be adjusted down to almost zero newtons with virtually no delay. This allows small robots to handle and analyse samples of active ingredients, DNA, tissue, urine or blood on wafer-thin pipetting plates safely and without damage.



Solenoid valve with media separation for dialysis machines









Name > FGK Clinical Research GmbH

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State > Bayaria

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edgar.fenzl@fgk-cro.com

Website > www-fgk-cro.com

www.fgk-rs.com

www.fgk-pv.com

Number of Employees > 230+

Founded (year) > 2002

Areas of Activity > Full service CRO (contract research organisation) offering a complete range of clinical development and consulting services all over Europe and the US:

| Regulatory Affairs

| Project Management and Monitoring

| Medical Safety

| Data Management/Biostatistics

| Medical Writing

| eSolutions for Clinical Trials

| Quality Assurance

FGK Clinical Research has two

daughter companies:

"FGK Pharmacovigilance" and

"FGK Representative Service". enabling us to offer our clients

pharmacovigilance services including

services of QPPV and PMSF management as well as legal representation for non-European

customers conducting clinical studies or seeking marketing authorisation within the EU/EEA.

External > BVMA - Federal Association of **Collaborations** Contract Research Organisations

Company Overview

FGK Clinical Research is a Europe-based CRO of an ideal size for cooperation with smaller and mid-sized medical device, biotech, or pharmaceutical companies. FGK was founded in 2002 and currently has 230+ employees. Covering all phases and areas of clinical development, we have experience in every important medical indication, including in particular oncology, cardiology, neurology, dermatology, and gastroenterology. Broad knowledge in alternative therapies completes our expertise. Besides our services for drug development, we also help to guide all kinds of innovative medical devices through the increasingly demanding framework of clinical investigations.

We directly supervise international projects and operate Europe-wide, with staff located in our headquarters in Munich, in our branch office in Berlin, and in our subsidiaries in the Czech Republic, Hungary, and Poland. Our in-house CRAs monitor many European study sites themselves. For additional countries and sites in the US/ Canada, we have suitable long-term partners.

Our Approach to a Project

The main philosophy for FGK is to prepare and conduct studies in close cooperation with the sponsor. Thus, we not only closely interact with our clients throughout the project but long beyond, as maintaining a good relationship forms the basis for long-term cooperation. Our operational team works hand in hand with all other departments involved. This also applies for the project manager, who is the central contact person delivering all required information to the sponsor. Timely approvals and efficient trouble-shooting are achieved through a combination of centralised project management and local monitoring, as well as local expertise in regulatory submissions within the country of study conduct.









Services

Regulatory Affairs

- Consulting on regulatory topics
- > Review of study documents (e.g. protocol, informed consent form, labels)
- CTA with submission to authorities and ECs

Clinical Operations

- Project management, primary liaison for sponsor communication, status reports, etc.
- > Feasibility, contract negotiations, site management, monitoring, etc.

Medical Safety/Pharmacovigilance

- Adverse Event Management and assessment/reporting
- > Drug safety, medical monitoring and coding of medical terms
- > Pharmacovigilance also visit www.fgk-pv.com

Medical Writing

- Investigator's brochures, study protocols, ICF and subject information
- > Clinical expert reports, clinical publications, IMP and submission dossiers

Data Management

- > CRF design and review, clinical trial databases
- > Data validation, processing and cleaning, external data handling, CDISC SDTM

Biostatistics and Programming

- > Study design, sample size calculations
- > Statistical consultancy, analysis plan, programming and reporting
- > CDISC ADaM

Quality Assurance

- Audits of investigator site, database and system audits, internal audits
- > SOP composition and implementation

eSolutions

> eCRF, IWRS/Drug supply, eTMF, CTMS



Name > GROB-WERKE GmbH & Co. KG

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State > Bavaria

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Email > Stephan.Kowalski@grob.de

Website > https://www.grobgroup.com/en/

Social Media > in 🗸 🗅 🖸

Number of Employees > 8,400

Founded (year) > 1926

Areas of Activity > | Complex metal cutting systems with focus on the automotive industry

| Entire assembly systems for automotive powertrains

I Since 2008 – Universal machining centre for supplier industry, medical industry, tool and mould industries, aerospace industry, general mechanical engineering, energy technology

| Since 2021: Addition of the 4-axis

| Automation solutions

| Electromobility: Systems for stator, rotor, and electric motor assembly and for battery and fuel cell assembly

| Expanded cutting-edge technologies:

| Software development

| Thermal spraying technology

| Machining of frame structure parts

| Machining of chassis parts

| Turbocharger machining Since

| 2022: Presentation of the first GROB Liquid Metal Printing Machine (GMP300) from the additive manufacturing sector

Annual Turnover > €1.6bn (22/23)

Member of





GROB-WERKE: Your competent partner in the machining of medical devices

Whether implants, prostheses, or medical instruments: when it comes to medical technology products, the quality has to be one hundred percent right. The dependable and highly precise universal machines from GROB meet the high requirements of the medical and pharmaceutical sectors and guarantee the reliable manufacture of sensitive workpieces. With its state-of-the-art automation and digitisation as well as expert know-how and service, GROB meets the challenges of tomorrow with productive solutions together with its customers.

As a global, family-owned company, GROB-WERKE has been developing manufacturing systems and machine tools for more than 95 years. Its customers include the world's leading automotive manufacturers, their component suppliers, and other companies from a broad range of sectors such as aerospace, tool mould-making, and mechanical engineering. This heritage gives GROB a huge and broad experience in its portfolio, from universal machining centre to highly complex manufacturing systems, and on to manual assembly stations – waiting to be transferred to their customers' production in medical technology. GROB accompanies its customers in the optimisation of production from the machine, through the process and its automation, to digitisation.

With the G150, GROB has now a G-module that fits small working pieces. The formula for success of its innovative machine concept is the horizontal axis configuration. There is no other concept where the Z-guide is closer to the workpiece, guaranteeing an extraordinarily high stability:

- Maximum reliability and accuracy in repetition
- Exceptionally high stock removal performance with a long service life
- Use of short, low-wear tools
- Highest shape and position tolerances for complex components

GROB's unique axis concept and the use of torque motors as standard enable:

- Combination of operations
- Innovative CAM machining strategies
- > Reduced impact of chips due to overhead machining



Most efficient processing of free-form surfaces with excellent surface quality

For getting the maximum out of the working piece, customers can optimise their machining processes with GROB's 100 application engineers and commissioning engineers worldwide and use the unique advantages of the G-module. Close contact with all renowned tool manufacturers and CAD-CAM manufacturers makes it possible to combine customer processes and the highest productivity with maximum process safety!

Due to the combination of ergonomics suited to a workshop and automation capabilities, the G-Module is suitable for both a job shop environment as well as for series production. On top of that, customers can increase the potential of the machines with GROB automation solutions. GROB offers solutions tailored to medical technology, from workpiece handling and pallet handling to small production cells. The customer can be free of possible sources of error by integrating and automating other work steps.

The software application GROB-NET⁴Industry is the enabler for the digital future. Increasingly strict regulations with fluctuating batch sizes and a growing number of variants, as well as individualisation, present conventional production systems with unsolvable problems. With its GROB-NET⁴Industry software solution, GROB offers a way of productively mastering this complexity. The digital products create manufacturer- and control-independent transparency, guarantee product quality and process reliability, and automate the necessary documentation. With this, GROB closes the circle towards an autonomous, productive, and completely process-reliable production. Service is the guarantee for a long and satisfied partnership, and GROB has always seen itself as a long-term partner to its customers. For GROB, as one of the most important and oldest partners of automotive groups, excellent service worldwide, the shortest reaction times, and fair prices are a matter of fact. From 24-hour service and a comprehensive range of spare parts and training courses to professional machine maintenance and analysis: GROB's service spectrum offers customers a comprehensive range of services and is available worldwide thanks to its global production plants and service branches.



KERN-LIEBERS Group of Companies

Name > CARL HAAS GmbH

Address/P.O. Box > Dr.-Konstantin-Hank-Str. 18

Postal Code/City > 78713 Schramberg

State > Baden-Wuerttemberg

Contact Person > Jacek Nowinski

Telephone > +49-7422-567-117

Email > info-ch@kern-liebers.com

Website > www.carl-haas.com

Number of Employees > 185

Founded (year) > 1904

Areas of Activity > | Medical products

| Plastic-metal-composite parts

| Precision springs for measurement

and control technology

| Garter springs

Passion for Your Success

Since 1904, the name CARL HAAS has stood for high precision products. Our experience is invaluable in the intensive engineering of medical products used in diagnosis and therapy. We concentrate on products made of wire and strips, such as guidewires (classes IIa and III), stone baskets and graspers, reinforcements for tracheal catheters, ureter prostheses, stylets, and assemblies laser-welded according to specification.

From the raw material to the finished product, everything is managed by HAAS. State-of-the-art technologies such as laser welding are used in the manufacturing process.

Continuous improvement has led to a top level of knowledge and competence, guaranteeing reliable processes and the high quality of CARL HAAS products. The quality management system is certified according to DIN EN ISO 9001, 13485, 14001, and 50001.

Within our KERN-LIEBERS Group, we can combine know-how from different areas and can even support our customers in development. With our 44 locations and around 7,000 employees worldwide, we have the opportunity to be close to our customers. A true onestop-shop store from the inquiry to series production.

Guidewires

Our extensive experience in the development and manufacture of guidewires in different configurations and materials allows us to reliably offer you high-quality products – from prototypes to high-volume production.

Stone extractor baskets

The innovative product range of stone extractor baskets from CARL HAAS is the ideal surgical option to remove kidney and bladder stones. CARL HAAS has developed a series of products with different numbers of wires in various shapes made of stainless steel.











Micro-turned parts

Decades of manufacturing experience: macro knowhow for micro precision-turned parts down to diameter 0.2 mm.

Canted coil springs

Our laser-welded coil springs are used for reliable yet flexible mechanical connection, contacting, shielding or as a support element.

Assemblies

Our wide range of technologies enables us to produce hybrid assemblies for you as our customer, including in clean rooms.

Special solutions

All prototypes and small batches of our special solutions for medical technology are produced according to your specific requirements. We process all stainless steels according to DIN and AISI, including common implant materials.

Precision grinding

Production of tapered and profiled wires with different grinding technologies as plunge grinding, centerless grinding, CNC-grinding. The ground wires are used for high-precision needles for medical-aesthetic treatment as well as for corewires of guidewires.

Laser welding

Our laser welding technology is used to weld different components. We also use the laser welding technology to generate hemispheric guidewire tips.

Coiling

With our coiling machines we produce coils according to customer specifications and for the production of our guidewires.



Name > HAHN Automation Group

Address/P.O. Box > Liebshausener Str. 3
Postal Code/City > 55494 Rheinböllen
State > Rhineland-Palatinate

Telephone > +49-6764-9022-0

Email > sales@hahnautomation.group

Website > www.hahnautomation.group

Social Media > 🖬 in 🗅 🖸

Number of Employees > 1,800 Founded (year) > 1992

> Areas of Activity > Special machinery, automation, and test technology in the MedTech industry

Your Global Solution Partner for the Efficient Production of Medical Devices

With the development of automation solutions for manufacturers in the highly regulated MedTech industry, we support those who aim to improve the quality of life for patients worldwide. The demands placed on the automation technology employed in production equipment are accordingly high to meet rigorous quality standards.

We offer:

- Compliance with GMP- and GAMP-related quality standards
- > Process-oriented and customer-specific development
- Scalable and innovative technologies

With a focus on quality and precision, we offer a wide range of products and services—from consultation on automation, feasibility studies, and design for manufacturing to building complex production lines. Our expertise is based on more than 30 years of experience in providing custom automation, assembly, test, and inspection solutions as well as state-of-the-art applications for the MedTech market.

Comprehensive Project Management

We support customers worldwide in developing tailor-made automation solutions that optimise their production processes. From manual stations to semi-automated cells and full production lines, our experts work in sync with your process – collaborating with your engineers while taking on the planning and implementation of the equipment to ensure that customers can concentrate on their core business. A global network of service specialists at over 20 locations worldwide is always available for maintenance and change request inquiries.

By using digital twins, we can train plant operators before commissioning and virtually test future production. As a digital image, the twin not only reflects the structure but also the behaviour of the system, which simplifies the simulation of subsequent optimisations in the later life cycle.







Global Footprint

We offer our customers development, production, and logistics in various European countries, the US, and China. International project teams work closely together to ensure automation solutions that were initially manufactured in Europe can easily be implemented in other countries using the same technology.

We are constantly working with our partners in the fields of image processing, laser application, and material handling to offer the latest trends and technologies to our customers. These innovative solutions enable us to meet the growing demands of the MedTech industry.

Cross-Industry Expertise

The HAHN Automation Group is the global solution partner for factory automation. The company stands for industry-specific know-how, an extensive project portfolio, and a global organisation with a focus on providing service all from a single source.

Whether Automotive, Electronics, MedTech, or Consumer Goods - the HAHN Automation Group offers a wide range of technological expertise that our team can transfer internally to any project. This gives customers access to a network of cross-industry best practices and worldwide support.



Name > HAMAMATSU PHOTONICS Deutschland GmbH

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Postal Code/City > 82211 Herrsching

State > Bavaria

Contact Person > Philip Waldner

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Email > info@hamamatsu.de

Website > hamamatsu.com

Social Media $\rightarrow \mathbb{X}$

Number of Employees → > 100

Founded (year) > 1986

Areas of Activity > Manufacturer of components and systems

Light-powered innovation

Our mission is to benefit society through the development of technologies that capture, measure, and generate various types of light. That is why we re-invest at least 9% of our yearly revenue into research and development – to maintain cutting-edge quality across 90 types of image sensors, light sources, components, and systems with capabilities that span the spectrum from x-ray to infrared.

Sensors and emitters for visible and invisible light

We are one of the only companies in the world that develops a wide range of both light sensors, such as photomultiplier tubes and photodiodes, and light sources such as lasers, LEDs, and measurement lamps. The components we manufacture measure and generate not only visible light, but also ultra-low, ultraviolet, infrared, and x-ray light.

Components, modules, and systems

Our light sensor and light source components are also available as modules and units with dedicated circuits. These devices can be incorporated into systems we develop, such as optical measurement systems, imaging systems, and image analysis systems.

These products are used in a wide range of applications, ranging from everyday technology such as smartphones to measurement instruments that support cutting-edge academic research.





Detecting disease as early as possible

All human beings are susceptible to the risk of disease, which is why early diagnosis is crucial. Hamamatsu Photonics manufactures high-performance devices optimised for medical use, such as positron emission tomography (PET), mammography, and X-ray CT. Throughout the world, our devices play an important role in medical examinations by detecting diseases such as cancer in their early stages.

Medical and bio instruments are a major industry and these are the application for which our products are ideal. Hamamatsu's experience in this market as well as the high quality and diverse range of products we can supply, makes us the ideal long-term business partner over the entire life cycle of your products and beyond.





Name > HealthCapital - Cluster Healthcare Industries Berlin-Brandenburg

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Postal Code/City > 10623 Berlin

State > Berlin

Contact Person > Dr Kai Bindseil (Cluster Management)

Telephone > +49-30-46302-463 Email > info@healthcapital.de Website > www.healthcapital.de

Social Media > X in

Areas of Activity > | Technology transfer between science and industry

| Initiation and support of networks

| Support for technology-orientated **Startups**

| Funding support for innovative project concepts

| Providing and presenting regional life sciences information

| Building and coordinating scientific and interdisciplinary networks

| Establishing contacts among experts from all disciplines

| Organisation of events and seminars

Collaborations

External > | Founding member of the Council of European Bioregions - CEBR

> | Member and contact point in Berlin for the Enterprise Europe Network (FFN)

| Member of Global Health Hub Germany

Berlin Brandenburg ... a leading hub for life sciences and healthcare

The Berlin-Brandenburg region is Germany's "health capital" and one of the leading international life sciences locations as it is both home to the German government and the centre for healthcare industries. The region's distinction is anchored in its unique research and clinical landscape, as well as its ability to closely link the key players in life sciences and healthcare. Medical technology, in particular, is a strong driving force within the Berlin-Brandenburg HealthCapital cluster generating innovation and growth there and beyond.

... MedTech meets Innovation

Over 350 medical technology and digital health companies are located in the German capital region. These include market leaders such as Ada Health. B. Braun. Berlin Heart, BIOTRONIK, Caresyntax, Eckert & Ziegler, Karl Storz, ORACLE Cerner, Ottobock, the Novanta company W.O.M. WORLD OF MEDICINE, and Zimmer Biomet. The main activities are focused on digital health, medical imaging, cardiovascular support systems, minimally invasive surgery, as well as orthopaedics. The region is also characterized by a variety of players from diverse technological fields. Expertise in optics and photonics, industrial production, new materials, biotechnology, connected health and many more pave the way for innovative medical technology in and from the capital region.

... Key technologies: Artificial Intelligence and Additive Manufacturing

The innovative power of the German capital region around AI is demonstrated by a significant number of healthcare startups. They are pushing the boundaries of traditional healthcare with AI solutions. There is also a very strong research landscape in the field of AI and data exemplified by several research groups at Charité, the Berlin Institute of Health (BIH), the Berlin Institute for the Foundations of Learning and Data (BIFOLD), the German Research Center for Artificial Intelligence (DFKI), just to name a few. A most recent showcase example is the TEF-Health consortium (Testing and Experimentation Facility for Health AI and Robotics), an EU-wide project



involving 50+ partners led by the Charité with the aim of improving and accelerating the validation and certification of AI and robotics in medical devices.

The healthcare sector also offers a variety of exciting use-cases for additive manufacturing where, for instance, personalized prosthetics or implants can be developed by using these techniques. Besides the opportunity for enhancing their business, companies within that segment profit from business networks, e.g. Medical goes Additive, as a knowledge and transfer platform. In addition, the AMBER initiative (Additive Manufacturing Berlin-Brandenburg) promotes innovation in this area.

... where startups meet grownups

With their innovative spirit and digital expertise, startups deliver fresh solutions for digital transformation in the healthcare industry. The German capital region is home to over one hundred digital health startups, and the numbers are growing each year. State-of-the-art technologies such as machine learning, artificial intelligence, and big data accelerate new applications. The regional startup ecosystem is highly self-organised and offers young pioneers a broad range of events such as meetups, barcamps, seed camps, and hackathons. A large number of incubators and accelerators specialized in healthcare topics (digital health in particular) further support and fuel this ecosystem.

... offering service and support for players in the German capital region

The central contact and coordination office for all issues concerning life sciences and healthcare in the German capital region is the cluster HealthCapital. At the interface of business, science, and clinics, the HealthCapital cluster management drives networking and technology transfer, and supports companies interested in relocating to the region. Berlin Partner for Business and Technology and the Economic Development Agency Brandenburg (WFBB) are responsible for managing the cluster.

Meet us in 2024

DMEA, 9-11 April, Berlin MEDICA, 11-14 November, Düsseldorf



Name > Hobe GmbH | micro tools

Address/P.O. Box > Baindter Strasse 27

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State > Baden-Wuerttemberg

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Website > www.hobe-tools.de

Social Media > in

Number of Employees > 33

Founded (year) > 1971

Areas of Activity > | Micro Tooling | Solid Carbide Tools

Member of



Boundless enthusiasm for inovation

At Hobe, innovation results from motivation. Our medium-sized enterprise is perfectly dimensioned to foster an effective innovation culture. Thus, every employee is encouraged to contribute creative ideas and new solutions. As a company, we regard our clients' complex demands as welcome challenges, which we meet by delivering seemingly impossible solutions.

Our goal: optimum machining solutions for all industries

Hobe micro-tools are successfully in use worldwide, for example, in the manufacturing of medical instruments, precision mechanical tools, and electronic components. Whether as standard tools, special tools, or custom development: we offer the best machining solution for every industry and application. Our sophisticated tooling systems contribute to making our clients' production processes more efficient, with a convincing combination of innovation, product quality, and profitability.

Quality

We can thank our motivated, highly trained employees and their commitment to deliver our compelling product and service quality at all times to our clients. Accordingly, Hobe produces exclusively in Germany with development and and manufacturing all under one roof. All business processes are reviewed by a certified quality management system according to DIN EN ISO 9001 and are continuously improved. For us, quality means optimum product properties, tailor-made tool and process solutions, and a reasonable price-performance ratio.

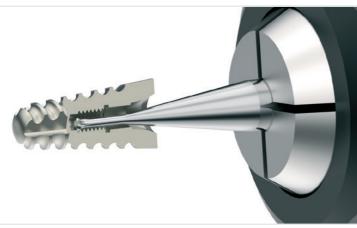
Medical technology

The manufacture of medical devices and components requires extraordinarily powerful tool solutions. This is particularly true for materials that pose difficult machining requirements, such as titanium or stainless steel. And this is where Hobe's solid carbide micro-tools excel. Its exceptional performance guarantees the desired dimensional and shape accuracy, as well as surface quality, at all times.

HOBE MICRO TOOLS









Furthermore, selected carbide grades with outstanding wear and flexural strength ensure a long tool life.

In medical technology, meeting manufacturing precision requirements presents increasingly complex challenges. Medical components are subject to progressive miniaturisation and sophistication. On the other hand, growing cost and time pressures make higher productivity a must.

Typical examples in this field are:

Pacemaker – internal shaping of electrode components Resectoscope - tube fitting (e.g. internal shaping) and lens fitting (e.g. internal grooving)

Implantology

Human implants and prostheses require the highest quality standards. This is the only way to avoid health risks and achieve a long product life. Accordingly, extremely corrosion- and wear-resistant materials are used in the manufacture of medical devices. The Hobe micro tools range includes a wide range of SC high performance tools that are ideal for medical device production.

Hard-to-machine materials such as platinum, titanium, stainless steel, and special alloys present us with special challenges in tool development - which we gladly accept. Through intensive exchange with customers, we have in-depth process knowledge in the field of implant prosthetics and dental technology.

Characteristic examples for implantology include: Dental Implant/Dorsal Stabilisation (pedicle screw) internal shaping (e.g. thread whirling, processing of multi-edge profiles)



Name > Hartmetall-Werkzeugfabrik
Paul Horn GmbH

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State > Baden-Wuerttemberg

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Email > info@de.horn-group.com

Website > horn-group.com

Social Media > 🖪 in 🇸 🖸 🔯

Number of Employees > 1,500 worldwide, ~ 950 of whom are in Germany

Founded (year) > 1969

Areas of Activity > High-precision tools and accessories

for radial grooving, face grooving, profiling, parting off, broaching, mirror turning, threading, machining pipes and sleeves, groove milling, slot milling, slot cutting, thread milling, polygon milling, thread whirling, brilliant finish milling, finish boring, reaming, non-circular rotary turning polygon turning high speed whirl milling and drilling. Additive manufacturing / 3D printing processes (selective laser melting), blanks, and wear parts.

Annual Turnover > ~ 300 million euros worldwide in 2022

~ 200 million euros in Germany in 2022

High-precision tools from Tübingen for the whole world

In 70 countries on every continent, companies in the automotive, chemical, aerospace, medical, and tool and mould-making industries work with tools from Paul Horn GmbH. In addition to 25,000 standard tools, the family-owned company has to date also supplied more than 150,000 special solutions to its customers.

Tools for medical technology

As a precision tool manufacturer, HORN is able to meet the challenges and to constantly work on developing new tool solutions and production strategies for medical technology – from micro end mills for manufacturing sensitive titanium spinal column implants right through to precision tools for grooving aluminium cooling ribs for a pump and heat exchanger. HORN is always building on its expertise in tool technologies in the medical sector.

HORN whirling technology is proof of this know-how

Key advantages of the whirling process include high cutting rates, long threads with high surface quality, deep thread profiles, short chips, multi-threads, and minimal tool loads. However, even with all these benefits, the user has to face various technical challenges. One important aspect is the materials used for bone screws. The cutting edges of the whirling inserts are subjected to extremely high loads when machining titanium, stainless steels, and other superalloys. With the JET-Whirling, HORN presents a whirling system with an internal coolant supply. By cooling the cutting edges directly. This system enables long tool life to be achieved. It also guarantees better surface quality on the workpiece which plays a major role in the production of bone screws. Every groove or ridge can be a breeding ground for germs.











HARTMETALL-WERKZEUGFABRIK PAUL HORN

Combined expertise for the medical industry

With the joint project funded by the Federal Ministry of Education and Research (BMBF), the participating partners INDEX, Paul Horn GmbH, Beutter Präzisions-Komponenten GmbH and the wbk Institute for Production Engineering at the Karlsruhe Institute of Technology (KIT) are demonstrating their expertise in the medical industry. Using new and modern manufacturing processes, the partners have tackled the challenges for economical machining of implants with multifunctional as well as non-round bionic designs. The focus was on the three manufacturing processes of non-circular rotary turning, polygon turning and high speed whirl milling.

Broaching an internal hexagon socket

"Manufacturing a hexagon in titanium is relatively easy using profile broaching. Broaching in series production in cobalt-chromium, however, is virtually impossible due to its high strength and the significant tool wear," says a German user from the medical technology sector. Due to this issue, HORN engineers proposed producing the hexagon socket using the shaping method. The method offers high precision and high process reliability, as the cutting geometry and the carbide substrate can be easily adapted to the material being machined. The first tests quickly found the solution required. "The shaping tool makes it possible to produce precise fits and the surface quality is very good," says the user.

Implant 4.0

Digitalisation has also been playing an increasingly important role with implants in recent years. You can already find intelligent implants that can be controlled via an app, in pacemakers or valves for regulating intracranial pressure. We can only speculate about what the future will bring but virtually every part of the body could be controlled using an intelligent implant in the event of a dysfunction: bladder, epilepsy and brain stimulators, retina implants, dispensing systems, and artificial pancreases - the list gets longer the more scientists, doctors, and engineers you ask. As the technology advances, HORN will be there, providing the tools required.



Name > Hugo Beck Maschinenbau GmbH & Co. KG

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State > Baden-Wuerttemberg

Contact Person > Timo Kollmann

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Fax > +49-7123-87268

Email > kollmann@huqobeck.de

Website > www.hugobeck.com

Social Media > X in D

Number of Employees > 110

Founded (year) > 1955

Areas of Activity > | Horizontal film packaging machines, flowpack machines, paper packaging machines, automation solutions. robots, and handling systems

Complete solutions for horizontal packaging in film and paper

HUGO BECK is a world leading specialist in horizontal film packaging machines, flowpack and paper packaging machines as well as automation solutions with the range of 3,000 to 18,000 cycles/hour. We provide a complete range of machine solutions for flowpacks, poly bags, and shrink packs as both primary and secondary packaging.

Our latest paper packaging solutions underline our commitment to the continued development of innovative machine technology and sustainable packaging solutions to help meet environmental objectives. Whether maximising production efficiencies and replacing plastic films with paper or minimising packaging materials used, our team is on hand to highlight savings that can be effectively achieved in the production of film and paper bags and shrink packs.

High-grade customised installations

While relevant for all industries, HUGO BECK's customised film packaging and automation solutions are particularly significant for the pharmaceutical and medical technology sectors. The packaging systems used, most of which are designed as high-grade customer-specific installations, guarantee the greatest possible precision of reproduction; in other words, packaging ready for sale, right from the very first product onwards. And it goes without saying that we meet the highest requirements in terms of cleanroom hygiene, documentation, and safety, while on the systems side, we achieve absolute traceability throughout the process (Track & Trace). Upon request we provide our clients with validation, qualification, and GMP certification service.

As the trend towards automation continues to increase. HUGO BECK also uses robotic systems as part of the packaging line and integrates various handling systems.













Safe and hygienic, airtight, and high-barrier packaging

The combination of air-tight, high barrier packaging and flexibility across different product sizes and bundles. makes HUGO BECK's flowpack machines ideal for applications in this area. The equipment is designed to conform to the highest documentation and safety standards. In addition, by processing a range of substrate solutions, materials such as composite and barrier films of various thicknesses, polypropylene and polyethylene mono-material, as well as Tyvek® can all be used for flowrapped primary packaging.

With flowpack machines, it is also possible to switch to paper-based packaging with a minimal sealable coating, which means that the paper still remains recyclable.

Additional functionality, such as packing under modified atmosphere (MAP), automatic film-changing devices, or the dispensing of leaflet inserts are only a few examples of user-specified options.

Upon request, all HUGO BECK packaging machines are available in stainless steel or hygienic design to meet the stringent requirements for packaging in this sector.

As an alternative to flowpack machines, we offer film packaging machines for poly bags and shrink packs. Here, the focus is more on product protection and transport, implemented as primary or secondary packaging. All types of film can be processed, including PE/PO/PP mono-material and bio films.



Name > ITK Engineering GmbH

Address/P.O. Box > Im Speyerer Tal 6

Postal Code/City > 76761 Rülzheim

State > Rhineland-Palatinate

Email > medizintechnik@itk-engineering.de

Website > https://www.itk-engineering.de/en/

healthcare

Number of Employees > 1300

Founded (year) > 1994

Areas of Activity > Standards-compliant and customized systems & software engineering, including software, electronics and mechanics, for different industries from healthcare and mobility to industry

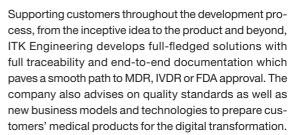
Shaping Tomorrow's Healthcare Technology

ITK Engineering GmbH is an internationally operating technology company that supports customers across all industries with the development of tailor-made systems including software, hardware and mechanics. In the healthcare business unit, which is certified according to EN ISO 13485:2016, ITK Engineering implements standards-compliant system and software solutions for medical products on its own responsibility up to the finished OEM product - from embedded real-time systems, web and desktop applications, medical apps, smart diagnostics solutions and data analytics up to hardware and electronic controls for medical devices and advanced medical robotics.

Since 1994, the company tackles technological challenges with passion and enthusiasm to develop innovative medical products together with its customers, drawing on the diversified skill-set of more than 150 healthcare specialists. With perfection, precision and passion at heart ITK is shaping tomorrow's healthcare technology.



ITK ENGINEERING



ITK Engineering, headquartered at Rülzheim, Rhineland-Palatinate, has ten branch offices in Germany, as well as worldwide in the USA, Japan, China, Spain, and Austria. ITK Engineering has been a fully owned subsidiary of Robert Bosch GmbH since 2017.







KENDRION

Name > Kendrion Kuhnke Automation GmbH

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Email > sales-ics@kendrion.com

Website > Kendrion.com

Social Media → 🗗 💢 in Founded (year) → 1928

Areas of Activity > | Solenoid Technology

| Fluid Technology | Control Technology

Kendrion Kuhnke Automation

Kendrion Kuhnke Automation stands as your expert in solenoid, fluid, and control technology, providing secure, precise, and innovative components and assemblies for diverse application areas.

Kendrion Kuhnke Automation is part of the Industrial Division of Kendrion N.V. and operates under the Industrial Actuators and Controls (IAC) business unit.

Solenoids & Actuators

In the development and production of solenoids and actuators, Kendrion Kuhnke Automation benefits from more than 100 years of experience and offers a broad product portfolio:

- Linear solenoids
- > Rotary solenoids
- Holding magnets
- Permanent magnets
- Oscillating solenoids
- Optical beam shuttersLocking solenoids & door lock systems
- Solenoid pinch valves

Our solenoids and actuators are universally applicable and mainly used in medical technology, such as dialysis machines, imaging systems, anesthesia and respiration equipment, cobots, dental units, and treatment & therapy equipment. The secure locks we provide are well-suited for demanding tasks in various applications, including centrifuges and disinfection equipment.

Member of







Valves & Fluid Control

In addition, Kendrion Kuhnke Automation is a manufacturer of smart pneumatic and fluid technology solutions and specialises in the development of custom valves, valve blocks, and pressure regulators. The portfolio consists of:

- Direct operated solenoid valves
- > Fluid isolation valves
- Mechanically & pneumatically actuated valves
- > Pilot-operated valves
- > Proportional valves
- Various pressure regulators
- Valve manifolds & assembly groups

Precise and reliable control of liquids and gases is essential for the high-quality demands of medical technology. Our valves are well-known for their high reliability, whether as a solenoid valve for e.g. pressurised air or a fluid isolation valve for e.g. dialysis fluids, as a manually or mechanically actuated valve for oxygen, or as a proportional valve for the dosing of potable water or gases. Kendrion valves can be found wherever optimum performance must be achieved within restricted space.

Customer-Specific Adaptations

For situations demanding unique materials or special properties, Kendrion Kuhnke Automation offers not only standard solutions but also bespoke customer-specific adaptations. Get in touch with us to discuss your specific requirements.

Learn more about Kendrion at www.kendrion.com.

KERN-LIEBERS

GROUP OF COMPANIES

Name > KERN-LIEBERS Group of Companies
Hugo Kern und Liebers GmbH & Co. KG

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Social Media > f in 🖸

Number of Employees > 6800

Founded (year) > 1888

Areas of Activity > Global manufacturer and engineering partner of medical

| Power Springs

| Constant Force Springs

| Spiral Springs

| Wire Springs

| Specialty Wires

| Guidewires

| Stone Extractor Baskets

| Micro Stamped Components

| Laser Technology Parts

| Plastic Metal Composites

| Hybrid Assemblies

Annual Turnover > Euro 787m.



Member of



OUR PRODUCTS FOR

KERN-LIEBERS, a medium-sized family company based in southwest Germany, is a global technology leader for the engineering and production of highly complex components and hybrid assemblies at over 40 locations around the world.

With extensive experience in the watch industry since 1888, KERN-LIEBERS has been successful also in the manufacturing of medical components and products for more than 30 years. Because of our wide range of in-house technologies, we design solutions for specific products, cleanliness and biological compatibility.

- Tailor made spring forces and profiles for specific Drug Delivery Systems (syringes, auto-injectors, inhalors, pump sprays).
- Diagnostics and laboratory equipment.
- Medical hygiene products.
- Cosmetics products.

Engineering partner of tailor made spring forces and profiles for specific drug delivery systems

(syringes, auto-injectors, inhalors, pump sprays etc.)

The KERN-LIEBERS GROUP of companies a size that pays off

When you put your trust in KERN-LIEBERS, you benefit not only from the strenght of an individual company, but from the unique expertise of a global group of companies that sets new standards every day. Standards in terms of quality, competence and performance.

Our experts in the medical technology sector are well known and established with their brand names like BOHNERT, EBERLE, GEBR. SCHMIDT, HAAS, KERN-LIEBERS, MEDER, PSM, BRUKER-SPALECK and SCHNÖRING.

KERN-LIEBERS is a member of the United Nations Global Compact Corporate Responsibility Initiative.







KERN-LIEBERS

BOHNERT Eberle GEBR. SCHMIDT BRUKER-SPALECK **MEDER**



KERN-LIEBERS GROUP OF COMPANIES

Special strip springs

> Power Springs

Power Springs are universal mechanical energy storage devices. They are used in many areas as a retraction element, and for weight compensation and torque storage. The hallmarks of power springs are there numerous working revolutions, increasing torque and a long service life.

Constant Force Springs

The special feature of constant force springs is their very uniform force-displacement characteristic, but variable characterists are also possible. They are used as tension/compression springs for long extensions with constant force and as torque generators with controllable spring characteristics.

Spiral Springs

Spiral springs used as torque generators for smaller angles of rotation where the stored energy serves as compensation or retraction torque. The torque/ angle of rotation characteristic curve for these springs shows an almost linear rise.

Stone extractor baskets

The innovative product range of stone extractor baskets from KERN-LIEBERS is the ideal surgical option to remove kidney and bladder stones. KERN-LIEBERS has developed a series of products with different numbers of wires in various shapes.



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Website > www.kern-sohn.com

Social Media > **fi** in **□ ⑤** Founded (year) > 1844

Areas of Activity > | Medical scales

| Height measuring systems

| Veterinary scales

| Organ scales

| Hand grip dynamometers

| Microscopes

| Microscope cameras

| Refractometers

| Laboratory balances

| Test weights

| Measuring instruments

| Calibration & verification services

KERN – Your competent partner for medical scales for hospitals, clinics, retirement homes, health care facilities, and doctors' practices.

KERN & SOHN was founded in 1844 and is Germany's oldest precision balance manufacturer. Already in its 8th generation, the owner-managed company manufactures high-precision scales. By concentrating on quality and developing customer-oriented products, KERN is synonymous worldwide with quality, precision, service, and reliability.

Especially in the medical environment, scales are subject to extensive standards and regulations that serve to protect consumers and patients. Beyond these standards, our certified quality management system and our many intensively trained medical product consultants ensure fast and competent product advice on all aspects of medical weighing technology.

KERN & SOHN offers its partners a wide and competitive range of scales and size measuring rods with and without medical approval (93/42/EEC), e.g.

- Baby scales
- > Personal scales
- Chair scales
- > Wheelchair scales
- Handrail scales
- > Bathroom scales and body fat scales
- Organ scales
- Laundry trolley scales
- > Hand grip dynamometers
- Size measuring systems
- > Veterinary scales

In the development of the medical scales and measuring instruments, attention was paid to materials that are easy and hygienic to clean. Special attention was paid to ergonomics to ensure maximum safety for the patient and maximum efficiency in operation for the user. All electronic scales can be operated by battery or rechargeable battery and are therefore independent of mains power. Thanks to the large number of models

Member of









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PROFESSIONAL MEASURING

with a wide variety of features, weighing and measuring data, interfaces, accessories, etc., the most diverse requirements and areas of application can be covered.

In addition, the weighing and measuring technology specialist offers a comprehensive programme of

- Microscopes
- Microscope cameras
- > Refractometers
- > Polarimeters
- Laboratory balances
- Industrial scales
- > Measuring instruments in the fields of force, layer and material thickness, torque, and sound and light measurement technology
- OIML test weights
- DAkkS calibration services, verification services

The trade customers and users of KERN products benefit from the many advantages on several levels:

- > Enormously wide range of weighing technology, measuring technology, microscopes, refractometers, as well as calibration services, verification services
- Fast delivery by express parcel service
- Immediate purchase or convenient instalment financ-
- > 3-year warranty on high-quality medical scales, microscopes, analytical balances, laboratory balances, industrial scales
- > Telephone hotline from 8:00 17:00 in the languages DE, EN, FR, IT, ES
- Catalogues and brochures in the languages DE, EN, FR, IT, ES
- > Product information, technical data sheets, etc. on the website available 24/7 in the languages DE, EN, FR, IT, ES, PT, NL



Name > Lemco Precision SA

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Website > www.lemco-precision.com

Number of Employees > 250

External > yes Collaborations

Lemco Précision SA has been a specialist in the production of high-precision screw machine pin and socket contacts as well as the production of inner bodies since 1965. We machine products of all sizes, including nano contacts.

Medical, Civil & Aviation and transportation are our main markets.

Our expertise lies in the production of highly sophisticated electrical contacts according to the drawings of our clients and in collaboration with our experienced professional engineers, designers, and plant technicians.

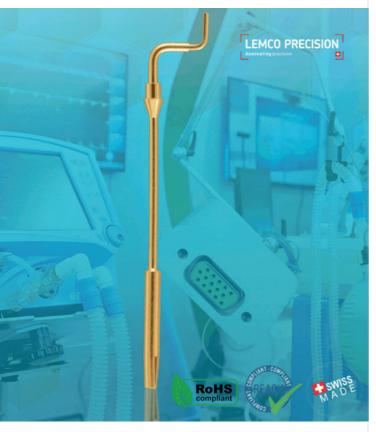
All of our products are manufactured to tight tolerances, from prototyping to the daily production of low, medium, or high volumes thanks to our 500 machines located at our two Swiss production plants. They are all subject to strict quality controls. The contacts we produce can be used in various types of connectors, circular connectors, rectangular connectors, triangle connectors, printed circuit boards (PCB), and custom-made products.

Our expertise is widely recognised in the production of crimp removable standard contacts according to the AS 39029 and EN3155 standards used in harsh environments, in addition to providing custom-made contacts and solutions for the international connection market.

No matter your request, we are committed to helping you and providing technical support in the development of your contacts, from prototyping to the delivery of mass-produced parts. Our team members are available to answer any questions you may have throughout the process.

Submit your design to us and we will produce it with a high level of quality control and a focus on 100% zero defaults target along with on-time delivery.

LEMCO PRECISION



A glimpse in some connectors we can be assembled onto:

- > Embedded electronics connectors
- > PCB
- > Push-pull circular connectors
- > Push-pull connectors
- > RF connectors
- Cable
- > Disposable plastic connectors
- > Hybrid circular connectors
- > Receptacle systems
- > Power cords with retention systems
- Lighted hospital-grade cords
- > magnetic medical connectors, etc.

A glimpse in some medical applications:

- > Patients monitoring devices/ systems
- Surgical robots
- Imaging scopes
- > Probes
-) Pace makers
- > Cardiac MRI equipment
- > Pumps
- Defibrilators
- > Diagnostic and digital imaging equipment
- > Therapeutic and implatable devices
- > Medical imaging (MRI Machines, CAT scanners...)
- > Electrophysiology catheters



Name > Waldemar Link GmbH & Co KG

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State > Germany

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Website > www.link-ortho.com

Number of Employees > approx. 1,200 (worldwide)

Founded (year) > 1948

Areas of Activity > | Medical devices

| Joint replacement

| Orthopaedic products

Member of





Waldemar Link GmbH & Co. KG

LINK is one of the world's leading manufacturers of implants for arthroplasty. Established by Waldemar Link in 1948 as a supplier to hospitals, the family-owned firm based in Hamburg has a clear mission – to improve quality of life for patients around the world by means of high-quality, innovative, and biocompatible joint prostheses. The company conducts its research, development, and production in Germany.

Full-service provider for arthroplasty

LINK is a successful full-service provider for arthroplasty. Subsidiaries and distributors around the globe ensure that LINK's endoprostheses and know-how are made available to customers all over the world in the shortest possible time. In China, the largest key market outside of Germany, the company is one of the market leaders in the premium segment. In Europe, LINK is one of the market leaders in the premium segment; Double-digit growth rates are being achieved there, as well as in the important future market of the USA. An important focus of worldwide sales is to open up developing markets.

Pioneer and pacesetter in the field of arthroplasty

The history of Waldemar Link GmbH & Co. KG stretches back to 1948. Even in those days, company founder Waldemar Link's philosophy was: In order to deliver the highest quality, there cannot be any compromises, while new developments and progress have to serve physician. patient, and the company in equal measure. Today, Helmut D. Link runs the company in the second generation - and in the same spirit. This firm conviction and the dedication of the staff at LINK, who number more than 1,200, have turned what was once a specialist supplier of hospital products into a pioneer and pacesetter in the field of arthroplasty. As early as 1963, LINK developed the first German total hip prosthesis, the St. George hip system. Ever since then, the company has placed emphasis on close cooperation with partners in medical practice in order to develop optimal solutions, while the LINKademy provides specialist training for surgeons, orthopaedists, and their surgical staff from orthopaedic hospitals around the world.









Problem-solver in revision and tumour surgery and in the development of patient-specific solutions

With the MEGASYSTEM-C. LINK is also recognised as a pioneer in revision and tumour surgery. Today, the company is regarded as a specialist and problem-solver for particularly complex cases. The MEGASYSTEM-C makes it possible to replace sections of bone in centimeter increments in a modular system. In addition, more than 40,000 patient-specific custom-made implants clearly demonstrate LINK's innovative strength and passion, from planning through to delivery. Top rankings in arthroplasty registries, such as the Swedish Hip Arthroplasty Register, confirm excellent long-term outcomes with LINK joint prostheses.

Uncompromising quality ensured by monitoring throughout the value chain

As a dynamically expanding company, LINK is constantly investing in the very latest technologies and production equipment. Continuous quality management begins at VACUCAST, the company's own precisioncasting foundry in Berlin, where castings are made from cobalt-chrome and titanium alloys, and only ends with the finished product, as sterile packaged implant. In combination with high-quality surgical instruments, these implants fulfil the key success factors of modern arthroplasty: uncompromising product quality, biocompatibility, and longevity.

LINK invests heavily in research and development

With the objective of enabling even more people to lead a pain-free life with maximum freedom of movement in the future, LINK works continuously on optimisation in all areas of arthroplasty. As such, the company not only invests heavily in research into new materials, production techniques, and surface treatments, but also focuses specifically on the challenges of arthroplasty, such as infections, luxations, abrasion, and implant loosening. In the course of research and development, LINK is working to find solutions to make joint prostheses even safer and more long-lasting.



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Number of Employees > 10

Founded (year) > 2020

Areas of Activity > | Regulatory Consulting and Services

Quality Management as a Service
| Vendor Selection and Vendor

Management

| Clinical Oversight Management

Lumis Life Science Consulting GmbH was founded in 2020 as a subsidiary of Lumis International GmbH with the focus to provide consulting to small and mid-sized medical device and biopharmaceutical companies for clinical trial outsourcing and regulatory activities.

Our services are divided into three pillars; quality management, clinical trial oversight, and regulatory services. Jointly with our customers, we develop tailored solutions to optimise their development programmes. We collaborate with a network of experienced subject matter experts to deliver the best service in each area.

Regulatory Services

Due to the new Medical Device Regulation (EU) 2017/745 (MDR), medical device companies must navigate increasingly complex regulatory requirements. Whether it's the impact of notified body availability, increased clinical evidence requirements, or changes to classification rules, the MDR can prove challenging to manufacturers.

Lumis has a team of experienced medical device regulatory experts who understand the MDR and have helped companies navigate the new requirements. We can support you with regulatory strategy, notified body interactions, technical file writing, clinical evaluation, QMS design and audit preparation, and more. Our broad understanding of medical device regulatory requirements enables us to devise efficient solutions that can reduce costs and expedite approvals.

Outsourcing the conduct of clinical investigations is cost-effective and efficient.

Small to midsize medical device companies are often facing the challenges of limited human resources. Thus, outsourcing of clinical trials is the common way to proceed with clinical development. Moreover, the survival of such companies is frequently dependent on successful, timely completion of clinical trials at limited budgets. Efficiency in managing clinical vendors is crucial. The safety of patients and the quality of clinical data must not be compromised.

LUMIS LIFE SCIENCE CONSULTING



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Especially during their first clinical investigations, it is not easy for the companies to decide on which activities to outsource or to perform in-house, thus, each activity should be evaluated in advance.

At Lumis Life Science Consulting we acknowledge the specific needs and priorities of medical device companies, while also reflecting their size, budget, and stage of product development. Our experts ensure the strategically selected CRO and vendors provide suitable services at the highest quality. We are specialised in outsourcing, vendor management, and oversight management, and have been building bridges between sponsors and CROs/vendors for over 20 years and have created successful partnerships.

Applying Key Performance Indicators to reduce risks and measure performance of outsourced activities.

In compliance with the MDR guideline, respective ISO Norm on Good Clinical Practise (ISO 14155:2020), Lumis' experts support the development and implementation of effective risk-based management systems for sponsors to ensure efficient and active monitoring and evaluation of vendor performance, applying Key Performance Indicators to oversee the progress of clinical investigations. We optimise the interaction between sponsor, CROs, and vendors by mastering different corporate cultures, expectations, and efforts, so your company can streamline the clinical development programme.



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Number of Employees > 55

Founded (year) > 1993

Areas of Activity > majesty GmbH specialises in providing full spectrum ERP solutions tailored to small and medium-sized enterprises in medical technology and machining industries.

Majesty - the ERP solution for small and medium-sized Medtech companies

For over three decades, majesty GmbH has been a leading expert in ERP software development, specialising in small and medium-sized enterprises in the medical technology and machining industries. With their innovative ERP solution "Majesty", the company successfully serves a broad customer base, comprising nearly 600 businesses and over 7000 users both domestically and internationally.

The core business of majesty GmbH includes the development, support and sales of its comprehensive ERP system "Majesty". Currently, the second generation of this software is available on the market. Thanks to its specialised expertise in medical technology and machining industries, gained over the decades, majesty GmbH distinguishes itself by tailor-made adjustments and solutions that meet the industry-specific requirements.

Seamless integration, modular flexibility, and user-friendly customisation

Majesty ERP enables optimal mapping of all business processes. Its modular architecture makes smooth adaptation for individual needs and seamless integration into existing software environments possible. Uniform operating concepts across all modules and an intuitive user interface facilitate efficient implementation with minimal training effort. Customisable fields, individualised input dialogs and tables ensure optimal support for any business process.

In addition to classic FRP functionalities in areas such as sales, procurement, production, and logistics, majesty GmbH also offers other essential modules for the medical technology sector. These include transparent and secure management of batch and serial numbers. Additionally, it offers an integrated licensing management module, ensuring compliance with the regulations of the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA). The straightforward logging and analysis of 8D reports help to continuously improve quality management & control.

Member of









Comprehensive services for optimal business operations

Moreover, majesty GmbH provides comprehensive services for implementing the software successfully and ensuring smooth operations. Among others, these services include introductory consulting, training, on-site support, help desk services and business management consulting for process optimisation.

30 years of experience and innovation in business software solutions

The company was first founded on January 1, 1993, in Spaichingen by Uwe Bader, under the name "UBiS -Uwe Bader Individual Software Solutions." The goal was to develop a standardised software solution for business management. As it turned out, there was a significant demand for such a solution among local small and medium-sized businesses in the medical technology and metal cutting industries. Since then, the company has been growing rapidly in both customers and staff. This growth led to the decision to build new company headquarters in 2020. In 2021, the company was renamed to "majesty GmbH", incorporating the name of the successful software in the company's name. As of early 2023, majesty GmbH is being led by Jan, Tim and Max Bader, three of the founder's sons. Uwe Bader, their father, continues to be involved with the company in an advisory capacity.



Name > mayr® power transmission

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Website > www.mayr.com

Social Media > f in * D

Number of Employees > 1,350

Founded (year) > 1897

- Areas of Activity > | Electromagnetic ROBA-stop® safety brakes for the holding, positioning, and securing of medical devices and furnishings such as surgerysupporting robots, X-ray devices, tomography beds, electric wheelchairs, surgical microscope stands, etc.
 - | Load-disconnecting EAS® torque limiters in medical devices such as tomography beds, etc.
 - | Electromagnetic, energise to engage ROBA®-quick brakes, for example in therapy devices for muscle build-up I tendo® DC motors, for example in devices used to look at X-ray images

Collaborations

External > VDMA Arbeitsgemeinschaft (German **Engineering Federation) for medical** technology

Member of



Safety does not allow for compromises

mayr® is an internationally-leading company for mechanical power transmission. Every day, clutches, couplings, and brakes made in the Allgau region safeguard machine movements worldwide. This task does not permit compromises on quality - especially in medical engineering, because the safety of patients has utmost priority at all times.

Whether in x-ray devices, surgical microscopes, electric wheelchairs, or in surgery-supporting robots - mayr® safety brakes have a wide field of application in medical engineering. High-tech devices often require individual brake solutions. For this purpose, mayr® power transmission provides a wide portfolio of applicationoptimised safety brakes based on market-tested series products. These fulfil individual customer wishes and distinguish themselves by the same quality, technical maturity, and safety as standard products. For example, during surgery the robot arm must not under any circumstances wobble or sink. The brakes must hold determined positions accurately and backlash-free, and simultaneously operate extremely quietly. This task does not allow for concessions in quality, because safety does not allow for compromises.

Short switching times and high performance density

Safety brakes by mayr® power transmission are tailormade to the requirements of medical engineering. They ensure reliable, constant holding torques throughout their entire service life and convince by extremely short switching times and high performance density despite low energy consumption. Furthermore, a long service life, minimal maintenance, and simple and quick installation make these brakes a particularly cost-effective solution. Depending on the requirements, the brakes are equipped with integrated noise damping. Every individual safety brake which leaves the mayr® power transmission works must pass a 100% inspection after complete assembly and adjustment. All measurement values determined are recorded with the corresponding serial number of the brakes in an electronic database.







This guarantees 100% traceability. These comprehensive tests and checks are a central component of the mayr® understanding of reliability and quality. They ensure that the values stated in the catalogue can also be reliably achieved and that the brakes function under all ambient conditions.

Reliable partner since 1897

Due to its quality standards, mayr® power transmission has gained the trust of many leading industrial companies as a reliable partner worldwide. Quality is not just theory at mayr® power transmission, but also an integral component of our corporate culture, which the company has incorporated in all processes, products, and structures since it was founded in 1897. The guiding principles of our renowned family-run company are safety, reliability, and innovation – not only in Mauerstetten, the German company headquarters, but also in all international locations. mayr® power transmission operates two further production sites in Poland and China, and is globally represented with sales subsidiaries in the USA, France, Great Britain, Italy, Singapore, Japan and Switzerland, and additionally with over 40 further national offices.

MIKRON TOOL

Name > Mikron Germany GmbH Abteilung Werkzeuge

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Website > www.mikrontool.com

Social Media > in 🗅

Number of Employees > 245 (worldwide)

Founded (year) > 1998

Areas of Activity > Development and fabrication of cutting tools

Annual Turnover > €45m Relevant R&D budget > €1.4m

External > DMQP (DMG MORI Quality Products)-

Collaborations Programme

Tools are our passion, small dimensions are our specialty, and hard-to-machine materials are our challenge. Every day at Mikron Tool is dedicated to achieving the best possible results in these areas.

Mission - Mikron Tool

We are working daily to achieve a leading position worldwide in the high-precision machining of small dimensions and challenging materials. This includes the regular development of new and unique tools as well as customer-specific solutions. In everything we undertake, a high level of competence is important. Focusing on our strong points is the key to our success. These include our well-trained and motivated employees, intensive development activities and investment in the most advanced production technologies.

MedTech Solutions - the tool range

The highest quality, precision, and process reliability are some of the main criteria when manufacturing medical devices, wether you are speaking about implants (trauma, prostheses or screws), instruments, or devices. This is exactly where our strength lies: in the development of carbide cutting tools for machining high-quality and biocompatible materials such as stainless steels, titanium, or chrome-cobalt alloys. We offer standardised tools for drilling, milling, and deburring in a diameter range from 0.1 to 8 mm as well as customised solutions up to 32 mm for all machining operations.

Latest innovations

A product is considered NEW at Mikron Tool only when it is unique and with high added value for the user. Without a doubt, this is true for every single CrazyLine product. For example:

For each titanium the right drill!

Titanium is a challenging material in terms of machining technology. Not all types of titanium are the same. Depending on if the material is pure titanium or alloyed titanium machining behavior varies. Therefore Mikron

Member of



MIKRON TOOL

Tool has developed perfectly tailored drills, the Crazy-Drill Cool Titanium, for the respective titanium grades, which guarantee high cutting values, process reliability and excellent hole quality in the diameter range from 1.0 - 6.35 mm.

Reducing machining time for bone plates

Integrated cooling, high- performance coating and carbide, adapted cutting geometry, all combined with an optimised cutting strategy - these are some of the features of our performance cutting tool package (CrazyDrill and CrazyMill product lines). With this we are able to reduce the machining time from two hours to 48 minutes for a distal radius plate made of titanium.

Technical support

How to produce a new part with the best adapted tools? What is the right tool for a new material? How to optimise quality and cycle time in an existing process? How to be more efficient and maximise my possible cost saving? Shall I use standard tools or rely on a special solution with combined tools? To answer all these questions, we are at your disposal with our Technology Centre and our specialised cutting tool team!

Quality made in Switzerland and Germany

All our tools are produced in Switzerland or Germany, where identical production facilities, machine programmes, measuring instruments, and skilled tool grinders guarantee the same level of quality for all our products.



Hemostatic clamp milled from solid

CrazyDrill Cool Titanium



Name > MULTIVAC
Sepp Haggenmüller SE & Co. KG

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State > Bavaria

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Fax > +49-8334-601-199

Email > muwo@multivac.de

Website > www.multivac.com

Social Media > f X in X □

Number of Employees > 7,000

Founded (year) > 1961

Areas of Activity > MULTIVAC is one of the leading

providers worldwide of packaging and processing solutions for food products of all types, life science and healthcare products, as well as industrial items.

Member of



No Compromising on Patient Safety: Sterile, Safe, Sustainable

In 1968, MULTIVAC launched its first packaging solution for sterile medical products. What at that time began as an offshoot of the core business of food packaging solutions is today a highly specialised business unit, which develops solutions for the automated packaging to GMP standards of medical items, pharmaceuticals, and biotech products.

Packaging Solutions from MULTIVAC – Flexible, Modular, Intelligent

MULTIVAC is well aware of the high demands placed on the packaging of medical devices. With its focus on maximum process security and reproducibility, as well as on the traceability of processes, the customised solutions completely meet the industry's specific requirements, from the fully automated packing of small batches starting from batch size 1 up to high volume production. MULTIVAC's packaging solutions range from product feeding and loading, to cartoning and palletising, including identification and inspection – covering common medical devices, such as combination packs, surgical supplies, laboratory supplies, diagnostics, implants and single-use products.

The company provides flexible and customer-specific packaging solutions, which are characterised by their modular construction. This means that both MULTIVAC components and 3rd party products from other manufacturers can be integrated very easily. MULTIVAC is also working on the development of digital solutions and services, so that it can offer companies the required added value. Thanks to its comprehensive sensor system and seamless digitisation, the RX 4.0 thermoforming packaging machine creates a completely new dimension in terms of maximum packaging reliability and consistent pack quality. The machine is also prepared for networking with the MULTIVAC Cloud, and this offers even more potential uses in digital services, for example.

The new R3 thermoforming packaging machine is suitable for packaging a wide variety of medical products, such as disposable syringes, labware or connectors,









products that are often produced in large batches and packaged in standard thermoformed packaging. Some of the features of the machine are its outstanding priceto-performance ratio, as well as its simple servicing and maintenance.

Sustainable Packaging Solutions for **Medical Products**

MULTIVAC also offers sustainable packaging solutions, which are increasingly gaining in significance in the medical products industry. There is a variety of packaging concepts available that make a significant contribution to saving consumable material and resources in the packaging process, as well as providing better pack recyclability.

Significant savings in consumable materials can be made with MULTIVAC machines, such as for example the reduction in film thickness, the close matching of the pack size to the product, and the optimised design of the pack format in the machine. Other potential savings can be achieved by reduced cross cutting waste, smaller partition widths between the packs, as well as narrower edge trims. MULTIVAC can also support customers, when it comes to better recyclability: The trend in the market is going away from multi-layer films, which cannot be recycled, towards fully recyclable polyolefin solutions. MULTIVAC machines are designed in such a way that they can run a wide range of materials without problems, and these include mono materials from PP or PE, as well as recyclable polyolefin solutions made of PE/PP.

By using MULTIVAC machines, customers can also save resources during the packaging process itself. Some machines already enable savings to be made in the compressed air and cooling water consumption, as well as energy savings through the use of electrical instead of pneumatic drives. Further developments in terms of sustainability are planned for the future.

You can find more information at: www.multivac.com.



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Social Media → fin 🗗 🖸 🕡

Number of Employees > 2,600

Founded (year) > 1942

Areas of Activity > | Circular connectors

| Modular connectors

| Electrical contacts

| Custom connector solutions

| Cable assembly

| Fibre optic

High-tech connector solutions for modern medical technology

Consistent performance and a high degree of failure protection are of vital importance in medical technology. As an interface specialist, we develop and produce custom systems and standard solutions for your medical applications. From MRI equipment to endoscopy, we design all our connectors in compliance with the strictest regulations and applicable standards, such as the Medical Device Regulation.

- High-speed and high-density technology
- > Sterilisable and autoclavable
- > EMC/EMI shielding
- Fiber optic, hybrid, and non-magnetic connection options
- Waterproof (IP50, IP67 and IP68) and hermetically sealed options
- Connectors with silicone overmoulding and cable assembly

Silicone-overmolded system solutions

Thanks to their non-sticky surface and other properties, silicone-overmolded system solutions are easy to clean, steam-sterilisable, flexible, insensitive to extreme temperatures, and tested in accordance with DIN EN ISO 10993-5. This makes them a hygienic and robust solution for everyday medical use.

To meet medical requirements, we offer customised silicone-overmolded system solutions consisting of connectors, overmoulded parts, and cables, including assembly and optional laser marking.

- Connectors with silicone overmolding and cable assembly
- Carefully matched materials for optimal haptics, hygiene, and durability
- > Partnerships with leading cable manufacturers
- We take care of testing, documentation, and certification for you









Fiber optic – fast and interference-free transmission

When it comes to challenging medical applications, we can offer a solution with our expanded beam technology that offers high-end transmission characteristics over up to 100,000 mating cycles. The excellent optical performance remains unchanged even under mechanical stress, environmental influences, and harsh ambient conditions. Since there is no direct contact between the contact ends. Expanded Beam connections are insensitive to contamination and can be easily cleaned. This ensures reliable transmission without any loss in the signal path. The portfolio also includes reliable physical contact technology that is characterised by very low insertion loss, which makes up to 1,000 mating cycles possible. For short transmission distances, polymer optical-fiber system solutions are also available as a cost-efficient optical connection.

- > GOF (multimode/singlemode) and POF system solutions
- > Fiber-only and hybrid systems
- > High number of mating cycles
- Available as a fully assembled solution

About ODU

The ODU Group is one of the world's leading suppliers of connector systems, employing 2,600 people around the world. In addition to its company headquarters in Muehldorf a. Inn (Germany), ODU also has an international distribution network, with production and product development sites in Sibiu/Romania, Shanghai/China, Tijuana/Mexico, and Camarillo/USA.

80% degree of vertical integration all competencies under one roof

ODU combines all relevant areas of expertise and key technologies including design and development, machine tooling and special machine construction, injection, stamping, turning, surface technology, assembly, and cable assembly. The ODU Group sells its products globally through its sales offices in China, Denmark, France, Germany, Hong Kong, Italy, Japan, Korea, Sweden, the UK, and the US, as well as through numerous international sales partners. ODU connectors ensure a reliable transmission of power, signals, data, and media for a variety of demanding applications.



Name > Oemeta Chemische Werke GmbH

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State > Schleswig-Holstein

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Website > www.oemeta.com

Social Media > in Founded (year) > 1916

Areas of Activity > Metal removal fluids, industrial fluids

What Counts is the Finished Part!

Every part machined for the medical industry must meet stringent requirements before it can be used on, or in, the human body.

The requirements for medical devices, equipment, and parts are strict, narrowly, and closely monitored and controlled. EN DIN 13485 describes the Quality Management regulations covering the auditing process and its implementation in the industry. The manufacturing process can be validated and audited despite using all kinds of different manufacturing aid fluids and materials if the final part passes all tests of the biocompatibility requirements in accordance with EN ISO 10993.

However, any contamination with critical material on surfaces or in contact with the part is a concern and should be avoided. Minimise the risk to ensure a safe manufacturing environment and process control.

So, what you want is a proven machining fluid and cleaner combination that eliminates any biocompatibility/cytotoxicity issues, or a fluid system that is proven not to contain substances of concern regarding the cytotoxic compatibility.

Oemeta has a comprehensive range of non-cytotoxic products that allow users to minimise operational and regulatory risk, document the product choice, the status, and the measures necessary to ensure an optimised application. The products are developed and proven to be the most efficient, easy to handle, and compliant with medical market requirements. They also provide optimisation opportunities during their lifetime in your machines.

Member of





Whatever your way of handling the regulatory challenges, it is most helpful to have a partner at your side who is available at your fingertips for a support call, and who is committed to your concerns and continuous process improvements.

Although Oemeta Chemische Werke GmbH has been in the market for more than 105 years, the coolant technology is designed for tomorrow's expectations. The requirements of medical technology manufacturing were considered in product development specifications for state-of-the-art coolants before a whole product line was tailored to MedTech. Oemeta has always been at the forefront of modern and visionary philosophies in coolant technology and is known for its best-practice expertise.

Oemeta is your partner of choice. Follow and contact us at: LinkedIn (https://www.linkedin.com/company/oemeta/)



Name > PIA Automation Amberg GmbH

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Postal Code/City > 92224 Amberg

State > Bavaria

Contact Person > Daniel Klieber

Telephone > +49-9621-608-0

Email > info@piagroup.com

Website > www.piagroup.com

Social Media > f in D

Number of Employees > 360

Founded (year) > 1975

Areas of Activity > Innovative, tailor-made assembly systems and production lines

Annual Turnover > 54 Mio EUR (2022)

External > VDMA Collaborations

PIA Medical – When only absolute quality counts

Demographic dynamics in society call for ceaseless new medical and pharmaceutical technologies and products. For more than 60 years, PIA Automation has been a reliable partner and innovative system vendor in the field of cost-optimised assembly of complex components.

PIA Automation develops and manufactures versatile, technically and economically mature assembly automation systems - including rotary indexing systems, linear transfer systems, customised systems and robot cells. The future-oriented complete solutions from PIA Automation are valued as the benchmark for specific assembly tasks in the medical and pharmaceutical industry. On our systems, medical devices such as autoinjectors, syringes, pens and inhalers are automatically manufactured and tested. We support our customers with manual workstations for clinical trials or proof of principles, with semi-automated production lines for small lots and with fully automated systems for serial production. With meditec® system technology, even the highest demands on precision, quality, cleanliness and availability can be achieved effortlessly.

Member of



PIA AUTOMATION

A high degree of standardisation, in connection with proven in-house expertise in qualification and documentation, enables PIA Automation to realise short time-tomarket cycles. Together with our customers, we develop testing concepts in order to design devices which are safe in functionality and handling. PIA Automation's design-for-automation principle achieves decisive cost advantages in regard to return on investment. Thus, the benefits of partnering with PIA Automation begin in the early stages of a design. Especially with sustainability and efficiency included in our primary objectives!

PIA Group overall employs over 1,800 people worldwide at 12 interconnected locations in Europe, North America and Asia. With know-how that has grown continuously over decades and more than 8,500 completed projects in the automotive, medical, consumer goods, electronics and testing sectors, PIA Group is now one of the world's leading automation specialists.









Made for MedTech™

Name > Premier Research

Address/P.O. Box > 3800 Paramount Parkway

Postal Code/City > Suite 400, Morrisville, NC 27560

Country > USA

Subsidiary > Premier Research (Germany)

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State > Hesse

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Website > premier-research.com

Social Media > X in

Number of Employees > 2,400+

Founded (year) > 1989

Areas of Activity > | Medical Devices

| Diagnostics

| Specialty Pharma

| Rare Diseases

| Cell & Gene Therapy

| Oncology

| Analgesia

| Dermatology

Neuroscience

| Pediatrics

| Women's Health

| Real-World Science &

| Late Phase Research

Premier Research is a clinical research, product development, and consulting company dedicated to helping biotech, specialty pharma, and MedTech innovators trans-form life-changing ideas and breakthrough science into new medical treatments.

As a global company, Premier Research specialises in the use of innovative technologies for smart study design and trial management to deliver clean, conclusive data to sponsors.

Medical Device

Whether you're conducting a 10-patient feasibility study or a 10,000-patient post-marketing surveillance study, we know all the steps — from scientific breakthrough to successful outcomes. Our experience spans just about every type of device, from transcatheter heart valves to dermatologic devices and everything in between. Many members of our medical device team come from manufacturers, so they know which questions to ask: What endpoints will global regulatory bodies expect and approve? What indication provides the best return on investment? Which claims make sense? What about pricing, and ensuring that your device qualifies for separate reimbursement?

We understand the differences among categories of medical devices, and our regulatory team tracks the latest global policy shifts and regulatory requirements.

Creative Solutions to your Most Complex Product Development Challenges

Wherever you are in the development life cycle, from raising funds and developing a regulatory strategy to patient recruitment and data analysis, we are positioned to help.

Our drug/device development and regulatory experts are relentlessly thorough, constantly asking why (and why not), taking nothing at face value, and being flexible enough to pivot and regroup when circumstances demand. We know



biotech and MedTech, and understand the passion and commitment that drives our sponsors. It is what drives us, too.

Our Service Portfolio

Clinical Trial Services

- > Site, Investigator and KOL Selection
- > Accelerated Study Start-Up & Trial Launch
- > Vendor Set Up, Management & Oversight
- > EC / IRB / CA Regulatory Submissions
- Cross-Functional Project Oversight
- Central Risk-Based Monitoring /
- Integrated Data Review & Analytics
- Quality Assurance
- Medical Management / Materiovigilance
- DSMB / CEC Management
- Adaptable Global Records Management

Product Lifecycle Services

- > Strategic & Operational Regulatory Consulting
- > Board Certified Medical Consulting
- Quality Assurance Consulting
- Medical Writing
- Human Factors & Usability Consulting
- National & Regional Representation Services
- Data Management
- > Biostatistics
- VRS / IWRS / ePRO / eCOA
- Strategic Sourcing
- > GDPR Coverage

At Premier, we foster a cross-functional, collaborative approach that brings together our MedTech experts, regulatory consultancy teams, and operational delivery teams to seamlessly support device innovators across the full product lifecycle.





Name > Process Sensing Technologies PST **GmbH**

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State > Baden-Wuerttemberg

Contact Person > Roland Scheurich, Managing Director

Christoph Arnswald, Key Account

Manager

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Email > info@rotronic.de

Website > www.processsensing.com

Social Media > in

Founded (year) > 1965

Areas of Activity > Measurement Instruments and **Environmental Monitoring Solutions** FDA 21 CFR Part 11/EU Annex 11

> **GxP** services including qualifications (thermal mappings), ISO17025 calibrations and validations.

Process Sensing Technology (PST) brings together well-established brands, each of which are trusted for the precision and reliability of their products, strong innovation and focus on customer service. Rotronic was founded in Switzerland in 1965 and is part of PST since 2017.

Within the Group, Rotronic is positioned as the competence centre for humidity & temperature measurement and environmental monitoring systems. This enables PST to offer its customers a uniquely broad range of measurement technology products that perfectly meet the requirements of biotechnology.

Biotechnology companies are subject to strict regulatory requirements and guidelines to ensure the safety and quality of their products. Environmental monitoring helps comply with regulations by tracking and documenting environmental conditions that could impact product quality and safety. Accurate and comprehensive environmental monitoring data is essential for maintaining data integrity and traceability.

Environmental monitoring of a laboratory and laboratory equipment is an integral part of the quality management system. It helps promote the quality and validity of data generated during the testing process and prevents fraudulent practices.

Trust in PST's real-time monitoring experience and our wealth of knowledge of all critical environmental parameters to comply with the GLP/GSP/GMP/GDP regulations and ICH/FDA guidelines.

Applications

- > Fridges
- Freezers
- Incubators
- Autoclave
- Cryogenic storage
- Laboratories & Cleanrooms
- > Rooms in general
- Storage & Transport



Measurement Instruments & Monitoring Solutions helping customers get insight into their applications Sensors Data Loggers

PROCESS SENSING TECHNOLOGIES

Measurement types

- > Temperature range: -200...850 °C
- > Relative humidity
- > Carbon dioxide CO
- > Oxygen O₂
- Differential pressure
- > Particle counting
- > Light (lumens, PAR, lux, etc.)
- Door monitoring (open/closed)
- > Webcams (pictures)

Additional services

Calibration

We offer a range of ISO-17025 and traceable calibration services, both within our facilities and onsite.

> Qualification

PST offers qualification services for rooms and equipment to help ensure the perfect environment throughout all facilities. The qualification will ensure the placement of the sensors within the various environments to ensure the highest quality of measurement data.

Validation

Validation includes the provision of documented evidence that a system was planned/produced according to quality guidelines, is tested against specifications and has been operated in a qualified manner since it was introduced. The PST real-time monitoring solutions are validateable and PST offers complete documentation, including IQ/OQ and PQ, to fully validate the systems.

> Consulting

PST offers a range of consulting services from the start of a project, including the URS, through the complete validation master plan, including developing SOP's and risk analysis. Maintenance and support ensure the long-term stability and accuracy of your system.

TEMPERATURE

RELATIVE HUMIDITY

DEW POINT

O2 OXYGEN

PRESSURE

AIR FLOW

ANY ANALOG
INPUTS

O10
DIGITAL INPUTS

Transmitters

GxP Services

I Compliant Software



Name > OUESTALPHA GmbH & Co. KG

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State > Hesse

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Email > info@questalpha.com

Website > www.questalpha.com

www.sugisponge.com

Number of Employees > >40

Founded (year) > 2020 as spin-out of Kettenbach,

active since 1944

Areas of Activity > Manufacturing and commercialization

of versatile medical grade sponge

material

Annual Turnover → **Double digit million** € sales

External > Active cooperation with several

Collaborations corporate R&D departments and

academic institutions

QUESTALPHA was spun off from Kettenbach in 2020. As leading manufacturer of high-performance absorbent materials made from cotton and regenerated cellulose, our expertise is dating back to the early 1950s with the launch of Sugi® medical sponge products. We cover the full value chain from research and development, production and logistics to marketing and sales of our product ranges. Our branded products have become indispensable solutions for doctors and hospitals in ophthalmology, ENT, dentistry, neurosurgery, microsurgery, hygiene, diagnostics, and wound care. Supplying our high-quality materials for developmental purposes and as versatile components in OEM products is supplementing our branded products business and enhancing our customer network in the medical device market.

QUESTALPHA's name emphasizes on our strategic realignment for further market expansion. While "QUEST" stands for the active pursuit, "ALPHA" underscores the best solution to be found for each individual customer.

SUGI® Products

All Sugi® Products contain our Sugi® medical grade sponge material made of pure cotton and regenerated cellulose with highest biocompatibility and tear resistance. Our material can absorb approx. 20 times of its own weight of aqueous solutions in a very short time. A soft elastic expansion is initiated and, depending on the area of application, a soft compression of the surrounding tissue is induced.

Sugi® Eve Spear

Ophthalmology places particularly high demands on surgical accessories. The highly absorbent Sugi® (sponge material) has proven to be very effective in the field of cataract surgery. With its tightly bound fibers and firm consistency when wet, Sugi® is ideal for diverse ophthalmic surgical procedures including LASIK. Sugi® outcompetes comparable materials in fluid wicking.

Sugi® RhinoSwabs

Rhino swabs have been specifically designed for functional endoscopic sinus surgery (FESS). Nasal surgery

Member of

::::BVMed





swabs with retrieval cord according to Prof. Dr. H. Stammberger are ideal for absorbing blood and secretion during endoscopic nasal surgery. The sponge material can absorb up to 20 times its own weight in aqueous solutions in less than 3 seconds. Sugi® absorbent swabs can also be used as a vehicle for various aqueous solutions.

Sugi® Plast

High quality components make Sugi®-Plast a unique product. Designed according to requirements of modern wound care products, Sugi®-Plast can be applied after vasopuncture, as well as in the field of secondary healing wounds.

SUGI® Inside

Customized raw material e.g. as a component in medical devices or for manufacturing processes of medical products. Individual development through our full service for component manufacturers, R&D specialists or material specialists.

Are you searching for a solution related to absorption, binding, retention, or separation of molecules in medicine and life science? Let us find out if our Sugi® material is suited for your purpose.

With Sugi® Inside we offer support and documentation during the entire development process of your customized raw material. A wide range of applications already benefits from the versatile physical and chemical properties of the unique sponge material.

In addition to our medical sponge activities, QUESTALPHA is both acting as a successful developer and producer of other medical devices and is seeking for additional applications.



Name > RAPA Healthcare

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State > Bayaria

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Website > www.rapa.com

Social Media > f in *

Number of Employees > RAPA Group Global: around 1000

Founded (year) > 1920 RAPA Group

Areas of Activity > RAPA Healthcare is a leading supplier and manufacturer of custom components, assemblies and complete systems for medical devices.

- | Product and system development and series production
- | Process development and integrated mechanical and plant engineering
- | New developments, product modifications and special solutions
- | Replacement of cost-intensive components with intelligent solutions
- | Smart valve solutions, such as hydraulic and pneumatic valves, media-separated solenoid valves, fluid management system assemblies, micropumps, etc.
- | Technology consulting and feasibility | Concept development and product
- | Mechanical design

definition

- | Pre-development
- | Prototype construction
- | Testing and simulation
- | Validation and documentation





Innovate with Us

RAPA Healthcare – your specialist for valve technology and engineering partner in medical technology. RAPA Healthcare is the medical technology division of the established RAPA Group, which has made a name for itself as an international development and technology partner as well as a preferred supplier for valves and comprehensive fluidic and mechatronic solutions. Our focus is on developing and manufacturing customised smart valve solutions and fluid components that are tailored to the specific needs of our customers in medical technology. In close cooperation with our customers, we turn innovative product and development ideas into high quality, production-ready products. RAPA Healthcare acts as both a system integrator and a supplier of modules and components.

Core Expertise

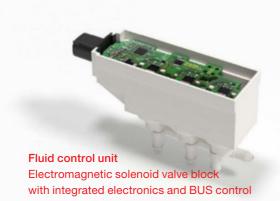
Custom engineering and in-house production

Unlike suppliers of catalogue products, we support our customers with comprehensive development expertise from idea to engineering to series production. Our range of services covers the entire value chain, from consulting and concept development to mechanical, electronic and software design, as well as prototyping and quality management. We carry out these processes with agile project management. Our team of highly qualified engineers and specialists design innovative, functional and economical solutions for medical and analytics equipment. Our products are manufactured in our own production facilities in Germany. While we handle the details, we relieve the pressure on your engineering team.

Product and Service Portfolio

Our portfolio includes individual components, complex assemblies or complete intelligent systems, which not only meet the ever-growing and complex requirements for medical technology components but also exceed them ('hidden needs'). They integrate seamlessly with your systems and offer the highest efficiency and reliability. RAPA Healthcare guarantees long product life cycles and availability, along with traceability and ef-

Media-separated solenoid valve for dialysis machines







RAPA HEALTHCARE

fective change management for components critical to risk mitigation. This includes:

- Valves and valve systems
- > Fluid management components and microfluidic solutions
- Integrated electronics and software

Customer benefits at a glance:

- > Time and cost savings: Benefit from time and cost savings by entrusting us with your development projects, allowing you to concentrate fully on your core areas of expertise. Our in-house research and development department brings the relevant know-how and technological expertise. We not only provide world-class resources, but also the tools you need.
- Quality assurance: RAPA has extensive in-house laboratory, simulation and validation facilities.
- > We are certified according to ISO 9001, ISO 14001, ISO 13485 and ISO 17025 to ensure the highest product standards.
- > Industrial excellence makes individuality affordable: Our company combines product and process development with production under one roof. This allows us to incorporate production and knowledge into the development phases right from the start. Combined with advanced automation, efficient production techniques and effective supply chain management, we can offer cost-effective, high-quality custom products.

With RAPA, you can be confident that your project not only runs but also surpasses all expectations. Our commitment: Smart solutions in time, in budget, in quality - ensuring maximum satisfaction and reliability.

Contact us: We engineer excellence for your application.

For more/further information, visit our website: www.rapa.com/healthcare



Name > Rösler Oberflächentechnik GmbH

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Website > www.rosler.com

Social Media > 🖪 in 🇸 🗅

Number of Employees > 1,500 worldwide

Founded (year) > 1933

Areas of Activity > Mass Finishing
Shot Blasting

Additive Manufacturing

About Rösler

For over 80 years, the privately owned Rösler Oberflächentechnik GmbH has been actively engaged in the field of surface preparation and surface finishing. As global market leader, we offer a comprehensive portfolio of equipment, consumables and services around the mass finishing and shot blasting technologies for a wide spectrum of different industries. Our range of about 15,000 different self-made consumables specifically serves our customers for resolving their individual finishing needs. Under the brand name AM Solutions we offer numerous equipment solutions and services in the area of additive manufacturing/3D printing. Lastbut-not-least, as our central training center the Rösler Academy offers practical, hands-on seminars to the subjects mass finishing, shot blasting and additive manufacturing.

High-quality surface finishing technologies for medical parts

The selection of a surface treatment process is the key factor that influences the functionality, performance and longevity of medical parts. Due to their precision, efficiency and economy, mass finishing and shot blasting are considered to be an indispensable part of the finishing process for a wide variety of medical parts in different manufacturing stages. Our flexible machines are able to do the surface preparation and final finishing starting from general cleaning, deburring, surface smoothing after casting, forging, stamping, machining, additive manufacturing, heat treatment, or surface preparation for plating, coating, or electro-polishing. This also applies to the final surface finishing stages for medical parts such as passivation, high-gloss polishing or the placement of a matte, non-glare finish on the surface of components.

Fields of medical application

Fields of medical application are endoprosthesis implants, trauma implants, spine implants, dental implants, medical instruments, endoscopy instruments, orthosis prosthesis and other medical and pharmaceutical devices.

Member of



BÖSLER OBEREL ÄCHENTECHNIK







Customer Experience Center worldwide

What's unique about Rösler's system is its integrative approach. Systems and processes are tailor-made to the respective processing requirements. Many subsidiaries of the Rösler Group are equipped with their own Customer Experience Center (CEC), with the latest in systems engineering. In order to capture data on the respective processing sequence, customer work pieces first undergo sample processing in the CEC. This decides which processing method will be used and with which peripheral devices.

Process development and process optimization

From sample processing to process design to mechanical implementation and expert after-sales service, you receive comprehensive solutions from a single source. The latest measurement technologies support our process development and optimization. More than 190 engineers and technicians work daily in our construction and development departments on individually tailored system solutions.

Global network

Besides the German manufacturing locations in Untermerzbach and Bad Staffelstein the Rösler group has a global network of 13 manufacturing/sales branches in Great Britain, France, Italy, the Netherlands, Belgium, Austria, Switzerland, Spain, Romania, Russia, Brazil, China and the USA. In addition, there are more than 150 sales agencies with years of experience standing ready to advise you.



Name > RoweMed AG - Medical 4 Life

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State > Mecklenburg-Western Pomerania

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Linui Intoerowomou.uc

Website > www.rowemed.de

Social Media > f in 🖸

Number of Employees > 160

Founded (year) > 2000

Areas of Activity > Customised Medical Plastic Systems

RoweMed AG – Medical 4 Life – is a German based medium-sized medtech company. We are specialised, in the development and manufacturing of customised medical single use systems.

Our focus is on complex systems for the fluid transfer for medtech, pharma and biotech industries, e. g. devices for the safe handling of sensitive pharmaceuticals.

To our customers all over the world we offer "turn-key" projects, from the first sketch to serial production, including the full documentation for products and projects.

Company history

The company RoweMed AG – Medical 4 Life was founded in 2000 by Roland and Gerda Wex. It started as a small engineering office with 5 engineers. In 2004 the first certified clean room (ISO 7) was established in Parchim.

The following years, clean room capacity was gradually expanded. RoweMed AG established injection moulding in cleanroom (ISO 8) and several other production technologies.

In 2022 RoweMed AG opened a new clean room facility which fulfils the highest standards as well as strict international requirements (GMP).

Business scope

R&D: The capability to develop medical plastic components and systems is the strength of our company. With our customers, we closely cooperate on challenging projects. We realise complex projects, from the first sketch up to a market-ready product, including CAD construction (solid works), prototyping, first series, process validation and project documentation.





It is essential for RoweMed AG to network with universities, medical centers and other research institutions and enterprises for our R&D activities. We therefor created a strong network of medical and technical experts around our company.

Production: RoweMed AG offers injection moulding, assembling our packaging under one roof. In our certified cleanroom facilities (ISO class 7) in Parchim employees produce single-part, small series and automated mass production. All common welding and gluing technologies are implemented.

Regulatory Affairs: In addition to the technical services, we offer the complete technical documentation according to all customer requirements (ISO 13485, Medical Device Directive 93/42/EEC. Medical Device Regulation (EU) 2017/745 FDA according to 21 CFR part 820).

Product programme

We offer a wide range of highly sophisticated medical disposables for infusion and injection technology, especially products for the safe preparation and administration of critical pharmaceuticals. Examples are infusion filters, injection filters, bottle spikes, infusion lines and infusion sets. All products are CE marked and labeled by RoweMed AG. Customer labeling is also possible. We sell our products worldwide through our strong network of distributors.

Based on our product program, we offer customised products for OEM customers in medtech and in other industries like pharma and biotech, where we realise complex tubing sets and filtration solutions.



Protecting Health.

Name > Sanner Group

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State > Hesse

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Website > Sanner-group.com

Social Media > in

Number of Employees > 600 Founded (year) > 1894

Areas of Activity > Device CDMO, Injection Molding

The Sanner Group, headquartered in Bensheim (Germany), with locations in Europe, Asia and the United States, has successfully expanded upon its roots as a global market leader in pharmaceutical desiccant packaging to become a next generation device CDMO offering state-of-the-art technologies for device development and manufacturing. Today, more than 600 dedicated Sanner employees supply products to more than 150 countries globally.

Digital Technology Resulting in Faster, Higher Quality Development

Using a Design for Manufacturing and Assembly (DFMA) approach combined with the efficient use of digital technologies from the earliest stages can accelerate development and improve quality. This is especially true during the design phase with the generation of detailed CAD designs. Thanks to injection molding simulations, the digital twin can help ensure that part design uses the right materials and that it will be manufacturable by a scalable injection molding process. At Sanner, this type of simulation is integral to defining optimised mold specifications and qualifications.

From the earliest stages of development, our engineers and automation specialists utilise Virtual Reality (VR) technologies to accelerate and derisk assembly process development. This allows us to seamlessly scale the device to industrial volumes, with shortened timelines from early development to series production. Using the latest VR technologies can help to achieve a more efficient assembly process that eliminates uncertainties and derisks the device assembly process from the start.

The importance of prototyping

3D printing allows Sanner to rapidly evaluate different concepts. After virtual prototypes made from detailed CADs, 3D printed prototypes provide the first opportunity to test a device or component in real haptic and optical forms. The FFF process (Fused Filament Fabrication) is a classic filament printing process based on thermoplastic and SLA (stereolithography) printing, which is particularly suitable



for medtech applications, and allows the use of biocompatible materials in accordance with DIN ISO 10993.

The Sanner flexible change mold system (additively manufactured mold inserts) in combination with a Babyplast injection molding machine provides a more sophisticated option. It can cost-effectively produce small batches of plastic injection-molded parts even under cleanroom conditions. Additively manufactured, fully functional mold inserts can be integrated into the company's own master molds using Sanner's in-house capabilities. This presents a cost-effective and rapid solution to generating the first samples made from the original material. Prototypes can be made available within a few days, or in some cases by the next day.

With Sanner technology, the development process can be shortened and potential defects can be eliminated at an early stage. In cases where there is a need to achieve a longer service life or to create more parts, in quantities to support clinical trials, aluminum tools can be the solution.

Get A State-Of-The-Art and Validated **Device Development Process**

Today, the Sanner Group uses a stage-gate development process called the Sanner IDP Process®. It starts with an idea that generates a device design which considers the necessary manufacturability and assembly principles right from the start. Our designers and engineering experts work with the help of modern technologies to develop a device which is processable in high volumes, with an excellent cost-ratio and that minimises risk. The Sanner IDP Process® is designed to deliver reduced time to production, minimised costs and greater regulatory compliance. All this comes with Sanner's long-standing commitment to high-quality, 100% process-controlled development, compliant risk management, and producing robust/reproducible manufacturing processes that can be successfully qualified and validated. The IDP-Process® also brings with it the flexibility to adjust to every project's needs, fully supported by a transparent and trusted customer relationship.



Name > SCHEUERMANN + HEILIG GmbH

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Website > www.sh-gmbh.de/en/

Social Media > **☐ in ☑** Founded (year) > 1957

Areas of Activity > | Development expertise and tooling

technology

High quality punching and punchingbending technology, spring technology, injection molding technology

| Automated assembly technologies | Integrated process technologies such | as cleaning and heat treatment

Annual Turnover > €85m

External > | VDFI (Verband deutscher

Collaborations

Federnindustrie) | EFB (Europäische

Forschungsgesellschaft für Blechverarbeitung)

| Fraunhofer-Gesellschaft

Member of



High quality metal & plastic forming solutions for the medical industry

For more than 66 years, SCHEUERMANN + HEILIG have been creating and manufacturing high-quality, cutting-edge, and innovative forming solutions in both metal and plastic, for a wide range of precision sectors, including the medical technology and healthcare industry.

Using advanced, state state-of-the-art technologies and hybrid production processes, we have many years of experience developing and manufacturing high-precision forming solutions and prototypes for auto-injectors and medication delivery devices, inhalers and respirators, blood glucose measurement and diagnostic equipment, needle protection systems and syringes, as well as, advanced endoscopy equipment.

To be more precise, we create and produce the parts that makes these systems work. Wherever you find crucial assemblies made from metal and plastic, stamped and stamped + bent parts, high precision, tension and compression springs, bent wire components, and the essential micro parts needed for medical equipment where total reliability is of the utmost importance, you'll find SCHEUERMANN + HEILIG.

Meeting the highest standards to achieve the highest quality

Our philosophy has always been to manufacture parts for industry that meet the most exacting standards. For decades SCHEUERMANN + HEILIG have chosen not only to meet the strictest performance standards but to exceed them where possible. These include ISO 9001, IATF 16949, ISO 13485, ISO 14001, ISO 45001 and ISO 50001.

We are a leading, premium developer and manufacturer of hybrid assemblies, stamped and stamped + bent parts, technical springs, and precision products made from advanced metal and plastics. We are totally committed to constantly questioning existing solutions and searching for more innovative ways of working.

SCHEUFRMANN + HEILIG

The development and series production of sophisticated complex assemblies is the focus of our work. For our first-class series production, course we create individual processes and tools and produce fully developed prototypes.

Our expertise in the use of hybrid technology - the automated combination of different metal components or metal and plastic elements to form complex assemblies - gives us an innovation advantage which benefits our customers worldwide.

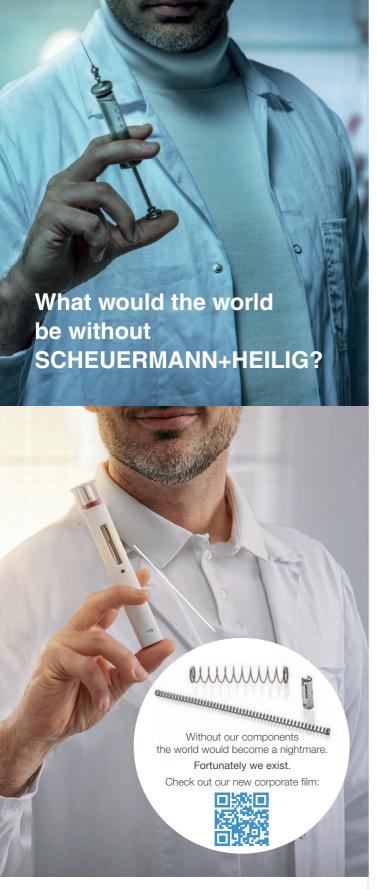
Of course, together with our customers, we also have the experience and the know-how to develop customtailored solutions, whether it's for individual components, assemblies, or system solutions.

SCHEUERMANN + HEILIG: Exploring the limits of what is possible

Our commitment to using innovative technologies, manufacturing precision, and the production of hybrid assemblies has always been and still is a family obsession. Our goal is nothing less than perfection at every level, right down to the tiniest detail. And because of this, since the company was founded in 1957 by Anton Scheuermann and Günter Heilig in Buchen-Hainstadt, Germany, we have grown to become world leaders in our industry.

In 1979 we expanded our operations and established SCHEUERMANN + HEILIG do Brasil in Atibaia. Brazil and have achieved premium supplier status to major international customers in the mobility, smart solutions, environmental, and building technology industries, as well as the medical and healthcare sector.

Visit our website and take a closer look at our range of products, our devotion to customer service, and how we can help you: www.sh-gmbh.de/en/





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Email > info-d@schneeberger.com

Website > www.schneeberger.com

Social Media → **ff in** Number of Employees → 1400

Founded (year) > 1923

Areas of Activity > | Medical technology

| Biotechnology

| Machine tool industry

Member of



Essentials for the Best

With a profound understanding of linear and profiled rail guides, as well as measuring systems for linear motion, SCHNEEBERGER linear technology has stood at the pinnacle of the industry for a century.

The name SCHNEEBERGER has become synonymous with innovation, extreme precision, and excellent quality. Our broad expertise encompasses linear guides, measuring systems, and racks, as well as high-performance ball screws and mineral casting. Additionally, we provide high-precision positioning systems, applicable under atmospheric conditions as well as in a vacuum.

High Precision, Innovative and Reliable

SCHNEEBERGER is a global leader in numerous application fields, including the machine tool industry, semiconductor industry, medical technology, bioscience, and robotics. Our pioneering spirit is also reflected in our status as one of the first and largest providers of crossed roller guides and integrated measuring systems. At SCHNEEBERGER linear technology we are committed to continuous evolution and delivering the best to our customers.

Customer-Oriented Employees

Our presence is truly global, with an extensive network of sales companies, sales engineers, and partners always within reach taking care of individual customer needs and ensure consultation and customer proximity. Production sites in Switzerland, Germany, Czech Republic, China and the US guarantee a high level of quality tailored for the specific markets.

Product Range for Medical and Biotechnology

SCHNEEBERGER offers high-precision linear technology with a primary focus on applications in medical and biotechnology. Our emphasis includes magnetic resonance tomography (MRT), computed tomography (CT), surgical microscopes, ophthalmic systems, scanner systems, liquid handling equipment, DNA

SCHNEFBERGER







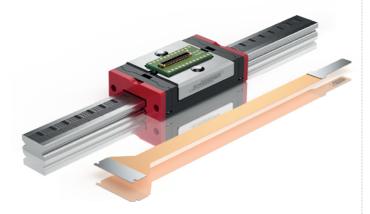


plate readers, 3D printing, cell analysis systems, and dental medicine. Precision, reliability, special designs, miniaturisation, integrated measuring systems, and application-oriented positioning systems collectively make us the ideal supplier in these application fields.

Guiding and Measuring in a Very Small **Footprint**

MINIRAIL represents the latest generation of miniature guides designed for demanding applications. These guides are exceptionally robust and demonstrate their capabilities in every application through high levels of smoothness, precision, and reliability. Derived from the proven MINIRAIL miniature guideway, MINISCALE PLUS stands out with its integrated optical position measuring system, offering precision, high speeds, and accelerations in the work process. It also boasts advantages such as low construction effort, quick installation and adjustment, consistent accuracy, and a long lifetime.

Highly Precise, Absolute Position Measurement

The SCHNEEBERGER Absolute Measuring System (SAM) represents a significant leap into the realm of Industry 4.0 for linear bearings. Guiding and measuring are seamlessly integrated into this unique one system solution. SAM currently stands as the smallest integrated absolute measuring system for linear guideway products, making it perfect for the tightest installation spaces. The system can be easily integrated into existing applications and is immediately 'plug and play' operational without the need for adjustment processes.

Your Reliable Industry Partner

As an innovation leader, SCHNEEBERGER develops the most effective solutions in collaboration with the customer. With over 100 years of experience, SCHNEEBERGER has been designing and manufacturing the highest quality linear bearing products and solutions. It serves as a reliable industry partner from concept and design to implementation.



Name > SCHUNK SE & Co. KG

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Postal Code/City > 74348 Lauffen am Neckar

State > Baden-Wuerttemberg

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Development Lead Life Science

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Telephone > +49-7133-103-3490

Social Media > ₹ × in × 🖸

Number of Employees > approx. 3,700

Founded (year) > 1945

Areas of Activity > Automation and equipment for robots

and production machines used in the life science areas:

| MedTech:

| Manufacturing and handling of medical consumables and products

| Robotics and automation in the human environment (e.g. surgical robots or rehabilitation devices)

| LabAutomation:

Handling in laboratory processes and analytical procedures

| Pharma:

Handling and automation in pharmaceutical production

Hand in hand for tomorrow

SCHUNK is the international technology leader in toolholding and workholding, gripping technology and automation technology. Approximately 3,700 employees in 8 plants and 34 directly owned subsidiaries and distribution partners in more than 50 countries throughout the world ensure an intensive market presence.

Through its pioneering spirit and innovative strength, SCHUNK continues to set new benchmarks in productivity optimisation for its customers. These customers benefit from an integrated range of components, applications, and services. The profound SCHUNK expertise that has grown over decades is the foundation for growth in a number of areas. SCHUNK is facing the current and future challenges together with its customers and Partners.

Automating the world of Life Science

As an experienced partner of the life science industry, SCHUNK knows that the requirements are not comparable to those of any other industry. Residue-free, highly sensitive gripping, corrosion resistance and cleanroom suitability are just three of the many standard features that are required, and for good reasons. SCHUNK focuses on the MedTech, LabAutomation and Pharma industry disciplines. In addition to flexibility and precision, absolute process reliability is required in all three areas. The reliability required for this, including application expertise, is part of SCHUNK's product and service portfolios.

Expertise for your application

SCHUNK's life-science portfolio includes components, applications and services for automation and clamping technology. Based on its extensive application experience, SCHUNK already offers ISO cleanroom-certified components, components configured with H1 greases (FDA compliant), VHP (H2O2) resistant materials, ATEX products and protective covers in hygienic design. In addition to the standard products, SCHUNK also offers modified versions and customer solutions tailored to





specific requirements. A team of specialists implements individual automation applications and from planning to certification in close cooperation with the customer.

MedTech

In the MedTech segment, we enhance machines and systems with the components and solutions needed for producing medical devices and consumables with highly efficient toolholding and workholding, gripping technology and automation technology. SCHUNK reliably meets the stringent requirements for lubricants, robustness and durability in the medical technology sector.

LabAutomation

Systematically recurring procedures are at the core of many laboratories. In the area of LabAutomation, SCHUNK provides the appropriate components for automation. Everyday issues in the laboratory environment include gripping and moving reagents as well as sample carriers for measuring and analysis equipment. For this purpose, we offer compact and easily combinable systems from the fields of gripping technology and automation technology.

Pharma

In the production of pharmaceutical products such as tablets, powders, creams and liquids, purity and quality are always top priority. The reliable and highperformance automation units from SCHUNK are ideally suited for this purpose. They ensure transparent, errorfree and structured processes, maximum efficiency, process reliability and cost-effectiveness.



Name > Seco Tools GmbH

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Social Media → f × in 🖸

Number of Employees > 4,000

Founded (year) > 1936

Areas of Activity > | General Engineering

| Automotive

| Medical

| Aerospace

| Power Generation

Seco-Tools – your partner for machining solutions

Seco is one of the world's largest providers of comprehensive metal cutting solutions for milling, stationary tools, holemaking and tooling systems. For over 80 years, we have been more than just a cutting tool provider. We develop and supply the technologies, processes and supports that manufacturers depend on to maximize productivity and profitability.

Headquartered in Fagersta, Sweden, Seco is present in more than 75 countries via nearly 4,000 team members. All Seco employees across the globe share a family spirit, along with a passion for our customers and personal commitment to ensuring their success.

Seco employees take a practical approach to applying high levels of metal cutting competence to overcoming customers' challenges. Relationships built on trust and respect are vital to our success. We work closely with customers to understand their needs. We undertake cooperative ventures with universities and industry associations to monitor trends and develop solutions that meet the needs of unique segments. We partner closely with providers of complementary technologies to ensure manufacturers have access to comprehensively optimized solutions.

Seco is part of Sandvik Machining Solutions, the tooling business area of the Sandvik Group.



SECO TOOLS









Machining medical components is a challenge for you?

The medical industry has experienced substantial growth in recent years, a trend expected to continue due to a variety of factors.

The worldwide economic issues of the past several years have created a growing demand to reduce costs, leading to substantial research and development into new materials and processes. Additionally, higher levels of regulation have created a need for more predictable and stable manufacturing methods. As these trends continue, medical manufacturers will face the ongoing challenge of adapting to an evolving market.

Seco has worked closely with global medical manufacturers for decades, building a foundation of expertise that makes us a valuable partner to those serving the industry. We also partner with research institutes, universities and other industry entities to fully understand the challenges medical manufacturers face and develop the solutions to overcome them. Our own R&D focuses on the advanced technologies, tools, strategies and component solutions that will drive and evolve your processes.

As the medical industry continues to innovate and grow, Seco is here to help you understand and overcome the metal cutting challenges you encounter.

Visit www.secotools.com or contact us. Seco will support your challenges in machining your medical components.



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State > Saxony

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Social Media > in 🇸 🗅

Number of Employees > 300

Founded (year) > 1991

Areas of Activity > | Medical technology

| Automotive

| E-mobility

| Electrical engineeeering

| Electronics

| Renewable energies

Annual Turnover > €50m (2019)

Member of



Experienced system partner for medical technology

As an OEM, SITEC Industrietechnologie develops, manufactures, and delivers production systems world-wide for its customers and produces modules and components on a series scale for medical technology. To meet the specific requirements of medical technology, SITEC offers its customers comprehensive engineering expertise and many years of experience in the laser machining of materials, electrochemical machining, and automated assembly.

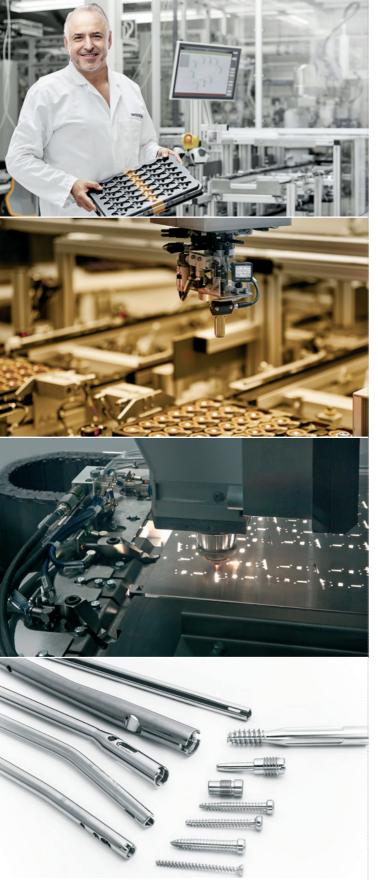
The range of materials that can be machined encompasses everything from steels and stainless steels to non-ferrous metals, such as titanium, Nitinol, aluminium, and copper, to various plastics and glass.

Laser machining of materials

Laser technology makes the high-precision, efficient machining of medical devices possible. The range of technologies includes laser welding, fine laser cutting, and laser hardening of extremely small local surfaces, as well as 3D micro-drilling, micro-structuring, and micro-removal. SITEC uses various laser-beam sources for this, such as CO₂, diode, fibre, disc, or ultrashort-pulse lasers, based on their optimal suitability for particular applications. Ultrashortpulse lasers are opening up brand new possibilities for ultra-precision machining in the micro-metre range, even for temperature-sensitive materials. Our experienced team of application engineers and designers will be happy to support you in the technological development of your products.

Electrochemical machining

Electrochemical machining (ECM) and its process variants offer maximum reliability and are particularly recommended for the manufacture of medical devices with above average requirements for quality and customer confidence, such as implants. Key applications include the deburring of drill cuts and defined chamfering. We can carry out sample machining at our application centre to show you the capabilities of the process.



Assembly technologies

The automation of assembly processes is our speciality. You can rely on our many years of experience in the automation of assembly processes and assembly technologies as well as the integration of testing processes, intelligent image processing, and laser processes. All assembly processes are controlled, ensuring 100% traceability.

Mechanical engineering

We develop and produce reliable production systems for flexible manufacturing in accordance with customer requirements and industry standards. Our portfolio covers everything from partially to fully automated assembly, laser, and ECM systems. Services for our customers include system planning, project management, design, production, and assembly.

A multi-stage process is used for preliminary acceptance (factory acceptance test - FAT) of the systems at SITEC and after delivery and recommissioning at our customer's location (site acceptance test - SAT). We provide professional support for the further validation process (PQ, IQ, OQ) through to the market release of your products.

Our service employees and worldwide partners in Europe, Asia, and America ensure you have access to fast, competent service at your site.

High-performance series production

Alternatively, SITEC offers you a ramp-up or series production on its in-house facilities and in certified quality. Our extended services include component assembly and pre- and post-treatment of parts. We use an IATF, compliant quality-management system attuned to the requirements of medical technology.



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Global Head of Pharma and Medical

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Social Media > ₹ × in × • •

Number of Employees > 6,000

Founded (year) > 1892

Areas of Activity > | Industrial automation

| Pharma automation

I Life Sciences & Medical Devices

| Medical technologies



Six-Axis Robots in Blood Plasma Processing

The handling of freeze-dried blood plasma requires stringent hygiene standards and a high degree of automation. The first step is to cut open plastic bottles containing thawed plasma and empty out their contents – a classic task for Stäubli Stericlean robots, which have been developed for use in hygienic and sterile environments.

For the past 30 years, HOF Sonderanlagenbau GmbH in Lohra has specialised in lyophilisation, and is currently the leading manufacturer of high-quality, technologically advanced freeze-drying systems for the pharmaceutical industry. The HOF portfolio includes systems for slicing open the plastic bottles in which the plasma is stored.

The process begins with one robot gripping four bottles by their top end and guiding them to the cutting station, which resembles a guillotine. A second RX160 six-axis robot positioned on the other side grips and steadies the lower half of the plasma containers.

At this point, the blade drops. The two robots empty out the contents of their bottle halves into draining trays. The human plasma – still in the form of a frozen core – slides down a channel into the defrosting tanks. The bottle halves are checked by sensors to ensure that they have been completely emptied, then placed onto a track leading to a disposal chute.

The debottling line can process up to 1,200 bottles per hour with a cycle time of 12 seconds. The throughput is so high that the specified production batch is ready and can be processed in minimal time – which is desirable for reasons of hygiene and process reliability.



The first of the two robots picks up four plastic bottles containing freeze-dried blood plasma that has been partially thawed ...



... and inserts them into the "guillotine". The second robot, positioned on the far side, grips and steadies the bottles by their lower end.



The top and bottom halves of the emptied bottles are discarded.

STÄUBLI TEC SYSTEMS

The choice of robot was easy for the HOF designers in this instance, and indeed in all of their other projects. Because robots are integrated into many of the systems the company supplies, it has defined standards for robotic applications and, with a view to the requirements of the pharmaceutical industry, has opted for the Stericlean models from Stäubli. These robots impress by virtue of their fast and precise handling as well as their suitability for washdown processes and thus for the hygienic automation of sensitive processes.

With this particular machine, HOF Sonderanlagenbau GmbH has come up with a real problem solver for pharmaceutical production. The debottling system, usually in combination with the upstream water bath thawing unit, is used by many of the world's pharmaceutical companies that process freeze-dried blood plasma.

The two robots work in tandem on either side of the cutting station. They ensure fast, precise and hygienic slicing of the thawed bottles of blood plasma without the need for human intervention. This results in a process with high productivity, maximum cleanliness, and enhanced flexibility: The system can be rapidly adapted to different bottle formats via the control system and the use of four-pronged grippers.



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State > Bavaria

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Founded (year) > 1949

Areas of Activity > | Pharma/Medtech packaging

| Plug&Pack

| Automationsystems

Cleanroom packaging protects against contamination

Cleanroom production and packaging are a very important issue because the primary packaging has to preserve the product and process quality. Primary packaging for pharmaceutical and medtech products needs to meet the highest quality requirements. Hygiene and cleanliness are basic properties for plastic packaging materials. STRUBL Packaging has installed a highly professional cleanroom manufacturing process for cleanroom packaging materials based on ISO 14644.

Cleanroom production based on ISO14644 has become the standard for all markets that have to meet the highest requirements in hygiene and cleanliness, e.g. the pharmaceutical, medtech, lifesciences, and healthcare industries. These products are covered by continous quality management monitoring. This applies to active pharmaceutical ingredients (API) as well as plastic devices and components, implants, instruments, tubes, inhalers, valves, application tools, and numerous products used for laboratory applications and testkits.

Before leaving the cleanroom environment, these products have to be packaged to avoid any damage and contamination during subsequent handling and transportation operations. Therefore plastic packaging materials are the suitable solution. Plastic packaging materials such as bags, side-gusseted bags, zipbags, covers, films, and tubes are used in every step of the cleanroom process value chain as primary packaging materials.

Cleanroom packaging – the best way to avoid contamination

To be sure, that the primary packaging meets the cleanroom requirements, these packaging materials have to be produced in a suitable cleanroom environment as well. Special risks have to be checked:

- raw material risks: migration between packaging material and product
- process risks: particle emission during the handling process





-) logistic risks: packaging specifications
- > product risks: sealability, seal strength, non-leaking seals

STRUBL cleanroom packaging

All products can be customised: the customer specifies dimensions and packaging requirements, such as labelling, as well as raw material conformities e.g. foodgrade/ medicalgrade/pharmagrade. All products are suitable for gamma irradiation. If needed all products can be designed with antistatic surfaces.

cleanzip - zipbags in cleanroom quality

STRUBL has developed a cleanroom zipbag. These reclosable bags are used for numerous applications, but until now these standard bags were not available in cleanroom quality. Cleanzipbags can be used for laboratory applications such as sampling, archiving, and intermediate packaging. Cleanzipbags are manufactured in a GMP-based production system and meet the high requirements of pharmaceutical applications required by the GMP guidelines.

bag-in-bag - bagsystems

"Bag-in-bag systems" are systems that combine two or three bags. The bags are already placed within one another to simplify the packaging process for the customer. Thus the customer reduces their packaging efforts: with one single packaging process, both primary and secondary packaging are fulfilled. This reduces excessive handling and the risk of damaging the products.



Name > TEBIT - The Medical Group

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State > North-Rhine Westphalia

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Social Media > in 🖾

Number of Employees > 120

Founded (year) > 1988

Areas of Activity > Manufacturer and solution provider for

medical technology applications.

 $\label{eq:conditional} \textbf{Focus on dental, trauma and medical}$

devices.

TEBIT - Medical technology ideas become reality

Since 1988, TEBIT – The Medical Group has embodied tradition and innovation in the Sauerland region of North Rhine-Westphalia. As a supplier and contract manufacturer, TEBIT produces components and assemblies for medical technology and implantology. TEBIT's identity is characterised by its familiar corporate culture and innovative spirit of development. Over 120 dedicated employees work every day to turn medical technology ideas into reality.

The two companies in the TEBIT Group, TEBIT Medical Devices GmbH and TEBIT Implants Technology GmbH, make it possible to offer customised solutions in medical device and system construction as well as in dental and surgical implantology.

Service portfolio

TEBIT supports its customers from the initial idea through to series production. Thanks to a highly qualified and experienced team of engineers and technologists, new components can be optimised during the product development process with a view to subsequent series production. Samples and additively manufactured prototypes, effective project management and standard-compliant documentation, including support for approval processes, round off the range of development support. The demanding requirements of the MDR and FDA for suppliers in medical technology are met and the long-standing certification according to DIN EN ISO 13485 demonstrates the commitment to the highest standards in medical technology.





The core competence of production lies in highprecision mechanical processing. Components made of stainless steel, aluminium, titanium and other medical implant materials are produced here. Thanks to a modern machine park consisting of sliding head automatic lathes, multi-spindle lathes and machining centres (5-axis simultaneous), the most diverse requirements can be implemented effectively and qualitatively.

Professional measuring technology, optical processes and a validated CAQ system enable efficient quality control and seamless batch traceability.

A wide range of technologies is available for finishing and surface treatment of the manufactured components. With a strong network and reliable partners in the supply chain, special requirements for surfaces of the highest quality and the necessary medical technology standards can also be realised.

In assembly, mechanical and electronic components are combined to form complex assemblies for medical device construction. Depending on requirements, it is also possible to carry out tensile, pressure and flow tests as well as customised assembly tests.

Since 2019, the service portfolio has been complemented by a modern ISO class 7 cleanroom, where validated cleaning and packaging processes ensure the highest process quality when packaging sterile components. Customised packaging solutions and efficient logistics make TEBIT a reliable partner for large and small manufacturers in the medical technology sector.



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State > Bavaria

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Email > info@tradex-services.com

Website > www.tradex-services.com

Number of Employees > 5 Founded (year) > 1998

Areas of Activity > Exhibitions

Tradex Services – Your full event service provider

As a highly specialized and well-established company we are supporting companies from Germany, Austria and Switzerland to grow their business presence worldwide - physically and digitally.

Therefore, we are collaborating with the largest exhibition organizers and are procuring floor space at many international renowned trade shows of different branches to offer exhibitors the comfort of showcasing their companies' capabilities easily and stress-free within our custom-built pavilion, individually or as a part of an official national or state pavilion. In additional to our basic services Tradex fairs and Tradex pavilion, based on our 20+ years of experience and the current business climate, we have developed unique digital tools to further enhance your company's presence on a global scale:

- Digital Exhibitor Catalogue (www.exhibitor-catalogue.com) - Be present all the
- > Tradex+ Stay connected all the time
- > Tradex^{app} Your mobile event companion

Our interlocking tools, know-how, high level of customer service and carefully selected partner network are constantly at your service to ultimately provide you with the best support your company deserves - so you can fully concentrate on developing your business network and lead generation, resulting in a healthy ROI.

Digital Exhibitor Catalogue (XC)

Our digital exhibitor catalogue (XC) - ,Your Promotion and Advertising platform' A smart solution for tomorrows standards, this tool helps prepare exhibitors to always be one step ahead. A combination of several smart applications that support Marketing / Networking / Promotion / Advertising platforms, our services takes international business development to a whole new interactive level.

Fully customized vBooths can be created, enabling you to present your products and services for specific target groups: worldwide - 24/7/365. A blend of several interactive communication tools, such as video calls, live chat and screen sharing directly on your vBooth.



All products / services can be linked to any relatable content, that will assist in the sales process, including webinars, tutorials, catalogues, social media, etc.... In addition to this, we offer an integrated .Business Appointment Scheduler', which helps you to optimize your time at live events by coordinating your meetings.

Our digital exhibitor catalogue (XC) includes not only your basic company details, but as well attendant to your physical show participation your vBooth and a youtubefilm, which shows the ,route to your physical booth'.

This gives your company the chance to stay visible all the time and provides you with a unique opportunity to announce your exact stand location at a specific trade show, further increasing your exposure, so your clients always will be able to find you during the show and you avoid missing business opportunities.

Our digital exhibitor catalogue (XC) obtains all provided information of your company and feeds your Tradexapp entry with all necessary information.

Tradex⁺

Tradex+ - ,Your Marketing and Networking platform' helps you to stay connected and promotes your company 24/7/365. Share up to 50 product and service pictures, videos, detailed descriptions and downloadable catalogues on a media-rich profile. Add social media links and personalized team contact information to your profile and streamline your business activity. Tradex+ is the foundation for all of our interactive digital services.

Tradexapp

Tradex^{app} - Your mobile event companion combines all features of Tradex+ and the digital exhibitor catalogue (XC), which enables you and your clients to stay in touch all the times. The app, available for IOS, android smart phones and tablets, qualifies anyone to interact with you before-during-after each show being held. Integrated search functions to check for profiles, products, etc. are linked to our company data base and digital exhibitor catalogue (XC). Additionally a Route-Planner and Appointment Manager helps you to organize and to coordinate your events.

Transline

Life Sciences

Name > Transline Gruppe GmbH

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State > Baden-Wuerttemberg

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Website > https://www.transline.de/medtech

Social Media ightarrow ightarrow in

Number of Employees > 150

Founded (year) > 1986

Areas of Activity > | Specialist Medtech translation

| Translation of trial documents

| Language consulting

| Terminology management

| Global content creation

External > MedicalMountains Collaborations

Life science content in 160 languages

Global markets offer great opportunities for your business. Our mission, and our strength, is to work with you to seize them. Highly professional translations are the key to accessing international markets. With 150 employees in Europe and around 5,000 specialist translators worldwide, Transline is one of the largest translation service providers in Germany. Our clients include many major global companies who value the quality of our translations, our excellent IT-supported project management, and the speed at which we implement their projects.

Certified – for quality and safety

With the safety of your users always in mind, we translate your Medtech texts with the utmost precision. ISO 17100 and ISO 13485 certifications attest to our high quality standards, making them binding, measurable, and verifiable.

Standard-compliant – and tailored to local markets

Our experienced, specialist in-country translators produce standard-compliant language versions, helping you as a manufacturer or distributor ensure regulatory compliance.

People and technology in perfect symbiolsis

Culturally authentic, easy-to-understand texts help guarantee user and patient safety, while the latest language technologies make sure your products reach their intended audiences quickly and effectively. Our industry specialists expertly translate even low-context strings and texts with restricted lengths, as well as test the usability of digital multilingual content for you.

"State-of-the-art" language technologies

The reason we have repeatedly ranked as "Best Language Service Provider for SMEs" is that we have designed all our processes around the needs and requirements of our customers. You benefit from simple, efficient workflows and clear, easy-to-understand texts that are ready for the international market in no time.



Translation for the entire medical products life cycle. Certified:

TÜV Süd ISO 9001 TÜV Proficert ISO 13485 LINQUACERT ISO 17100 LINQUACERT ISO 18587

01Design, **Development** and Testing

Product Launch

and Marketing

Approval

02

Regular

05 **Post Market** Surveillance

Market

Approval

Transline

"First-class" vendor management

The native speakers that translate for us meet strict criteria, which include holding a recognised university degree and having several years' experience in medical technology and clinical trials, respectively.

We only use our top language suppliers for your healthcare-related texts, and through our evaluation and feedback system, they are able to continually improve their performance.

"One-stop" language management

We cover Medtech in all languages and follow the medical product lifecycle from clinical trials to patents and e-health products, providing comprehensive translation services and language consulting, including:

- > Process consultation
- > Project management
- Tool infrastructure
- In-country review
- Desktop publishing
- Source text optimisation
- Back translation

What clients say about Transline

"With Transline's integrative portal solution, we have significantly increased our process reliability by eliminating manual steps. At the same time, we benefit from shorter delivery times, improved quality, and cost savings for translations. Moreover, all steps and corrections are clearly documented in accordance with the MDR." /// Dr Martin Koch, Head of the Technical Academy at DÜRR DENTAL SE

"Thanks to the close coordination and effective communication with Transline, we didn't have to worry about the translation during the CMS migration. This allowed us to fully concentrate on migrating the content." /// Florian Happe, Head of Research and Development, also responsible for product documentation at Richard Wolf GmbH



Name > TRUMPF

Laser- und Systemtechnik GmbH

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Industry Manager MedTech

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Social Media > in

Number of Employees > 18.352

Founded (year) > 1923

Areas of Activity > TRUMPF is a technology and market

leader in highly versatile machine tools for sheet metal processing and in the field of industrial lasers.

Annual Turnover > €5.4bn

TRUMPF was founded in 1923 as a series of mechanical workshops and has since then developed into one of the world's leading companies for machine tools, laser technology, and electronics for industrial applications. The company's mission is to further develop and digitally connect production technology, to make it even more efficient, precise, and future-proof. In doing so, TRUMPF works towards making manufacturing and its upstream and downstream processes more efficient. TRUMPF's software solutions pave the way to the Smart Factory, allowing companies to implement high-tech processes in industrial electronics.

The family company is headquartered in Ditzingen near Stuttgart, Germany and is represented by over 70 subsidiaries in all of the world's leading markets. Production facilities are located in Austria, China, the Czech Republic, France, Great Britain, Italy, Japan, Mexico. Poland, Switzerland, and the United States.

Expert in laser technology

The product portfolio of TRUMPF starts in the range of low-power lasers for e.g. marking and ends up with multi-kilowatt systems for the chip-producing industry. Between these poles a large variance in power, pulse length, wavelength, and beam quality can be offered. No matter if it is cutting, welding, cleaning, or marking of stainless steel, aluminum, copper, or plastics - there is a laser for each application. Furthermore, a large variety of machine systems is available.

TRUMPF is a strong and reliable partner for medical technology companies, mainly in the fields of laser marking, laser cutting, and laser welding, but also in metal 3D printing. Long-term success within the market is based on high-end technical solutions and a strong drive for innovation.

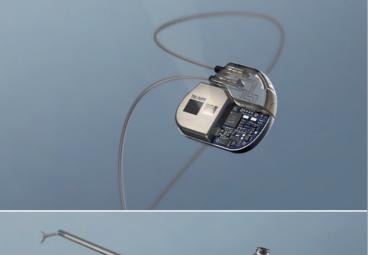
Laser marking

Laser marking is a process that has become indispensable when applying UDI codes. Nevertheless, every material needs the right laser to apply high-quality markings. For instance, the integration of pico- and femtosecond lasers into marking systems enables the so-called blackmarking process. This process is used to create durable, long-lasting UDI markings on metal surfaces - a manda-















tory requirement for the medical-device production. In addition, TruMark systems also realize processes related to the actual marking, such as quality control through image processing or communication with databases.

Laser welding + Laser cutting

The joining of complex products requires highly reliable manufacturing methods. The TRUMPF laser welding systems enable a broad range of benefits in precise and repeatable 3D laser welding of assemblies such as medical instruments. The large variety of welding optics and laser sources allows the optimal configuration for individual production demands. Implemented image processing and monitored laser power ensure consistently high-quality process results.

As a pioneer in laser cutting, TRUMPF offers sophisticated and robust technology for 2D and 3D cutting applications. Thanks to excellent precision and dynamics, even the smallest workpieces and devices can be processed without compromising on the high demands for quality and productivity.

Metal 3D printing

3D printing is shaping the future of industrial production. Metal 3D printing with TRUMPF offers the possibility to create a completely new product right from scratch that fulfills high quality standards. Starting with loose metal powder, our TruPrint machines economically print e.g. implants, like spinal cages (see picture), mold and die inserts for medical devices. CMF implants and more. In addition, further developments of in-line process monitoring and process automation make the technology even more reliable and reproducible.

To satisfy the high demands of medical technology, TRUMPF Laser- und Systemtechnik SE not only offers turnkey solutions including consulting and application support, but also provides expert advice in industry-specific topics such as equipment qualification. Together with its customers, TRUMPF acts as a solution provider with a strong focus on future trends and development projects.

Get in touch at www.trumpf.com



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Email > medical.technology@tyrolit.com

Website > www.tyrolit.com

Social Media → 🗗 💢 in 🖸 🖸

Number of Employees > > 4,400 Founded (year) > 1919

Areas of Activity > Grinding, cutting and finishing tools

for medical technology:

| Orthopedics (artifical knee, hip and trauma implant grinding)

| Medical equipment (bone rasps, drills, milling cutters, scissors, scalpels, tweezers, etc.)

| Dental (drills, files, burrs)

| Needles (hypodermic and sewing needle grinding)

| Guide wires

Annual Turnover > €727m (2022)

The Tyrolit Group

Tyrolit is one of the world's leading manufacturers of grinding and dressing tools as well as a system provider for the construction industry. Since 1919, our innovative tools have made an important contribution to the technological development in many industries.

Tyrolit offers tailored grinding solutions for various applications, as well as a comprehensive assortment of standard tools for customers all over the world. With roots in the heart of the Austrian Alps, Tyrolit combines the strengths of family values with a global vision and over a century of individual corporate and technological experience.

Tyrolit in medical technology

These days, humans are getting older on average than ever before. Since 1990, life expectancy in the EU has increased from 74 to over 81 years. This trend has a major impact on many parts of our life.

The trend of an ever-aging society has increasingly brought medical advancements and medical technology into the spotlight. At the same time, a long and active life puts a particular strain on our joints. Orthopaedics therefore plays an important role in the field of medical technology. Hip and knee joint operations in particular are now routine interventions. However, the dental industry accounts for the largest percentage of implants. Over one million dental implants are installed each year in Germany alone.

The demand for ever better and more durable products through the use of new materials in the production process is steadily increasing. With numerous system solutions and proven experience, Tyrolit is a competent partner for medical technology customers.





Due to the high requirements and small tolerances in this industry, partners experienced in manufacturing are needed to guarantee consistent quality of the finished products. With innovative grinding solutions. for example, Tyrolit ensures that hypodermic needles are sharp with no microscopically small barbs and that patients with new hips can get back to moving smoothly as quickly as possible.

In knee joint grinding Tyrolit offers a lightweight core made of natural fibres, which allows for a significant weight reduction. The N-LW (natural lightweight) core is not only lighter and more cost-effective, but also offers positive damping characteristics. In grinding femur components the use of superabrasive grinding tools is the industry standard and Tyrolit manufactures a doublelayered disc with a high abrasive layer and special shape that can be used for processing over the full 20 mm.

For the machining of hip joints Tyrolit offers a selection of various resin and vitrified bonded grinding and polishing sleeves. The productivity of the manufacturing process can be increased by using conventional or superabrasive grinding tools adapted to the respective application. For example, by using superabrasive tools, the cycle times for pre-grinding could be reduced from 10 minutes to 1 minute.

A third pillar of Tyrolit's medical technology portfolio is the processing of surgical instruments. An updated range of grinding and finishing tools is used for a variety of finishing processes. For more safety during surgical procedures, scalpels are sharpened with cool cut discs and finished with elastic or non-woven tools, thus guaranteeing the highest surface quality.

Tyrolit, a household name in all abrasive applications, offers customers also a dedicated application engineering support for the optimal use of its abrasive tools.



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Social Media > F in * D

Number of Employees > 500

Founded (year) > 1960

Areas of Activity > Cutting tools for:

| Medical and Dental

| Automotive

| Aerospace

| Energy

| Oil & Gas

Member of



VARGUS

VARGUS is a world leading developer, manufacturer, and supplier of high-quality, precision threading, grooving, turning, parting-off and hand deburring tools, Established in 1960, VARGUS is the cutting tools division of the NEUMO Ehrenberg Group, a multinational organization headquartered in Germany. With 13 international subsidiaries, a network of distributors, warehouses, and certified ISO 9001 manufacturing facilities, VARGUS serves customers in more than 100 countries around the globe. VARGUS is committed to providing products and solutions of the highest quality and excellent value. Vargus Deutschland GmbH offers necessary technical support for our customers to find the best tools, optimal cutting conditions, and to improve quality and efficiency. A comprehensive range of stock is available for sameday delivery in addition to our facilities for manufacturing special tools.

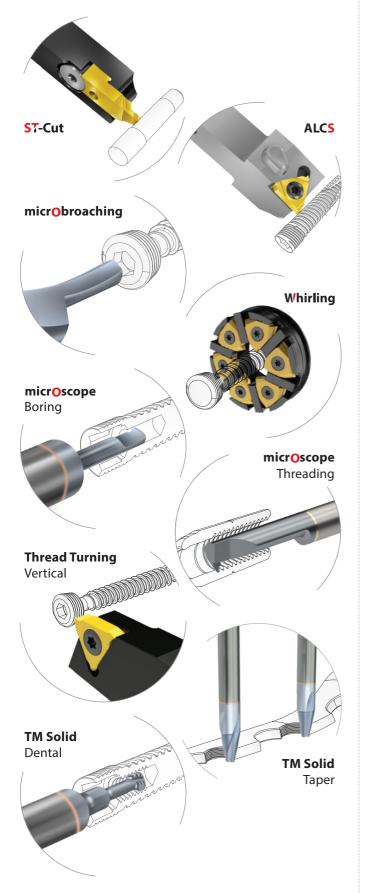
Introducing VARGUS solutions for the medical industry

Keeping up with the demands for mass production and special tooling for the Medical Industry, VARGUS provides an encompassing range of solutions for the precise and detailed applications used in this rapidly growing industry. Whether it be the manufacturing of miniature dental implants, bone screws, bone plates, tulip heads, or other exact medical components, our precision tools provide you with the excellent VARGUS quality so well known in the metal-cutting industry. Biocompatible Titanium and Stainless-Steel are the most common materials used in the medical industry. With the VARGUS knowledge and experience, our skillful engineers developed advanced grades highly suitable for the strict requirements of medical applications.

Vargus solutions for the medical industry ST-Cut Swiss-type tools

An innovative solution for machining small parts on Swiss type machines. Includes parting off, turning, grooving, and threading:

- Quick change of the insert inside the machine
- > High repeatability of the cutting edge on all axes
- > Cutting edge treatment for increased tool life



ALCS - thread turning toolholders

External thread turning toolholders for Swiss type machines with high pressure coolant:

- > Right, left, back and bottom coolant inlets
- > Two precise high-pressure coolant outlets
- Longer tool life and better chip evacuation

MicrObroaching

A modern design of broaching for Medical Industry requirements:

- Unique design for improved stability
- > Fits popular driven tools
- > Standard items for Hexagon & Torx

Whirling

For efficient machining of bone screws and dental implants:

- Fast machining with improved tool life
- > Fits popular driven tools
- VARGUS threading quality

MicrOscope

Micro machining solutions for boring, grooving, profiling, chamfering and threading in bores as small as 0.5mm:

- Chip breaker and coolant thru available
- Shrink holder for increased stability

Thread Turning - vertical

- Slim throat holders for tight spaces
- Multi tooth available

TM Solid - thread milling

A very large variety of solutions of solid carbide thread mills including:

- Taper tools for bone plates. Straight and helical flutes available
- > Reinforced throat for dental implant

VARGUS is your ideal partner, offering a wide selection of solutions for the most common dental and orthopaedic machining applications.

Follow us on social media and subscribe to our newsletter: vargus.de/newsletter



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Social Media > ☐ in × ☑ 🕢

Number of Employees > 500

Founded (year) > 1970

Areas of Activity > Contract development and contract manufacturing of opto-mechatronic systems and complete high-tech devices for medical & life sciences. laboratory technology, in-vitro diagnostics & analytics, laser technology, optical measurement technology, semiconductor technology, and additive manufacturing.

External > | SPECTARIS

Collaborations | WIN – WILD Integrated Network

| EIT Health

| Additive Manufacturing Austria

| HTS - Human Technology Styria

| Silicon Alps

| Medizintechnik-Cluster Business

Upper Austria

| Photonics Austria

| VNL - Verein Netzwerk Logistik

| qualityaustria

| IV-Industriellen Vereinigung

| Health Tech Cluster Switzerland

| StEP-Up

The WILD Group Your experienced partner in contract development and contract manufacturing

WILD is your technology partner for product development and serial production of opto-mechatronic components and complete high-tech devices. We develop and manufacture exclusively on behalf of our customers - world market leaders as well as start-ups - in medical technology, optical technologies, and industrial technology.

Our customers appreciate the combination of our core competences in:

- > Precision mechanics/mechatronics
- Electronics & software
- Technical optics

WILD is able to enter a project at every stage of the product cycle. No matter if it is still in development, in transition to serial production (industrialisation), or in the mature phase of the life cycle (production transfer). We solve complex problems with a flexible combination of suitable elements from our range of services:

Engineering Services:

- Mechanical design
- Optics design
- Software & electronic components design
- Lightsource design
- > Prototypina
- > Regulatory affairs

Assembly Services:

- Assembly of complex opto-mechatronic components and complete devices
- > Clean room assembly & assembly of sterile products
- > Validated and stable processes, ISO 9001, ISO 13485, MDR and GMP compliant, FDA approved
- Documented final testing and initial setup
- High-precision positioning of optical components through state-of-the-art centre turning equipment











Manufacturing Services:

- Mechanical manufacturing of precision parts:
 CNC milling, turning, grinding, eroding, etc.
- Surface Engineering:
 Galvanic surface treatments (electroplating), anodising, varnishing, blasting, printing, etc.
- Furthermore:
 All sorts of plastics manufacturing, sheet metal manufacturing EMS, etc.

Quality Management

- Process validation (IQ, OQ, PQ)
- > Risk analyses (PFMEA)
- Incoming goods inspection (FAI)
- Master Validation Plan (MVP)
- Certified and stable processes according to ISO 13485:2016 and ISO 9001:2016, Medical Device Regulations (MDR), and FDA regulations

Supply Chain Design

- > Strategic supplier qualification
- > Defined release process according to standards
- > Risk analysis (supplier, process, product)
- > Auditing of suppliers
- > Supplier evaluation & supplier development
- VMI Vendor Managed Inventory

Further Services:

- Value & Life Cycle Engineering
- > Production Transfer
- > Repairs & Refurbishments

We adjust our service packages to suit your requirements. Our broad range of technologies combined with a strong partner network (WIN: Wild Integrated Network) ensures stable processes across the entire product life cycle of your products.

Don't hesitate to contact us and let us support you!



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Social Media > 17 in D

Number of Employees > >1,200 worldwide

Founded (year) > 1988

Areas of Activity > Wipotec is a leading global provider of intelligent weighing and inspection technology.

> With a broad portfolio of checkweighers, X-ray scanners, Track & Trace systems, and innovative solutions for the mail and logistics industry, Wipotec serves our global retail business in many target industries.

Global leader for intelligent weighing and inspection technology

As a founder-managed company with more than 30 vears of experience, our value chain strategy is over 85% self-made. We provide customised solutions from a single source, beginning with hardware and software development, through production, to supply chain integration and maintenance. Our competence centre delivers premium quality: designed, engineered, and manufactured in Germany. Driven by our corporate philosophy - "Innovation. Passion. First." - we develop and produce unique machine solutions and technologies for OEM and end users in a wide range of industries at our head office in Kaiserslautern. At Wipotec, we value enduring, long-term partnerships and always put our customers first. "First" as in top priority.

Everything under one roof

All Wipotec products and integration solutions are developed in the modern Wipotec parent works in Kaiserslautern and built with the highest engineering skill. High quality and reliability paired with extraordinary performance characteristics and straightforward integration are achieved with the motto "everything from a single source". This philosophy of short channels is a guarantor for maximum quality control, the rapid application of new innovations, and flexibility in the realisation of your requirements. Irrespective of how unusual your application appears, the motto of our CEO and founder Theo Düppre that "nothing is impossible" drives us to the highest achievements while finding the optimal solution for you.

- Dynamic Weighing
- > Weigh Cells
- > Product Inspection
- > Track & Trace
- Marking & Labeling











Our standing

Certified to ISO 9001.

Our quality management system always ensures that customer expectations are exceeded. ISO certification is only the official stamp of our achievements, but the desire for continuous performance improvement comes from deep within us, from the heart.

Corporate Social Responsibility.

As a major regional and global employer, we are aware of our responsibility. Social commitment, an employeeoriented personnel policy, fair dealings with suppliers, and the conservation of resources are, for us, a natural part of entrepreneurship. With the Code of Conduct we commit ourselves and all our employees to strive for the best.

Energy-autarkic production.

Climate and environmental protection is not greenwashing for us. We care about the environment and how we can protect the earth within the scope of our influence. With our own solar park, a geothermal plant, halls and administration buildings in passive house standard, as well as vehicles, we are working towards complete energy self-sufficiency. But processes, plants, as well as our suppliers must also meet our high standards. We want to reduce emissions, use only regenerative raw materials, and act in an ecologically and economically sensible way.



Name > ZECHA Hartmetall-Werzeugfabrikation GmbH

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Website > www.zecha.de

Social Media → 🗗 💥 in 🖸

Number of Employees > Ca. 130

Founded (year) > 1964

Areas of Activity > | Medical and dental technology

| Chronograph industry | Automotive industry

| Tool and mould making

External > | AlienTools GmbH

Collaborations | MPK Special Tools GmbH

| ZECHA PRECISION TOOLS LIMITED

| CIMTRODE GmbH

For six decades, ZECHA Hartmetall-Werkzeugfabrikation GmbH has set the pace and established itself as a leading force in the realm of micro cutting, blanking, and forming tools. The company's roots in the chronograph industry not only underscore its unwavering dedication to crafting miniature tools of the utmost precision but also highlight its commitment to tailored tool solutions. Precision and quality form the cornerstone of their global presence across various sectors, including medical and dental technology.

Reliable Tools for the Dental Industry

To tackle the intricacies of inlays, onlays, bridges, and crowns, where precision is paramount, it's imperative to have top-tier milling tools, especially when working with challenging materials. ZECHA steps up to the plate by offering dependable diamond-coated mill cutters designed for the machining of zirconium oxide, cobalt-chromium, plastics, and wax.

Precise Tools for Implants

Beyond their patented series 462 of solid carbide whirl thread cutters, perfect for crafting cylindrical and precisely contoured internal threads required for implant posts and medical devices, ZECHA extends its offerings to encompass dependable diamond-coated milling cutters for working with zirconium oxide. Moreover, they supply special WAD-coated milling cutters tailored for cobalt-chromium, plastics, and wax – all essential for the production of dental replacements.

Perfecting TORX® Interfaces

The machining of titanium, stainless steel, and special materials in medical technology necessitates customised solutions at the highest caliber. Take, for example, the TORX® interface commonly used in medical applications to establish a secure connection between bone screws and screwdrivers. To mill the TORX® contour in titanium and stainless steel screws, ZECHA has engineered specialised micro-milling cutters that guarantee unmatched precision, surface quality, and long-term profitability.





YOUR TOOL **TECHNOLOGY** FOR THE MEDICAL **TECHNOLOGY**





IGUANA: LASER-SHARP AND **ULTRA-PRECISE**



KINGFISHER: WITH INSIDE AND SHAFT COOLING



QUEEN BEE: PROCESS RELIABLE WITH STEELS UP TO 58 HRC & SPECIAL MATERIALS

ZECHA HARTMETALL-WERKZEUGFABRIKATION

Expertise in Crafting Bone Plates

ZECHA's proficiency extends to demanding applications involving materials like titanium, stainless steel, and specialty alloys, a prime example being the intricate production of bone plates. For these exacting tasks, ZECHA provides high-quality, meticulously coordinated tool solutions.

Challenge of PEEK Machining

Addressing the unique challenges posed by difficultto-machine materials in the medical technology sector, ZECHA introduces the innovative IGUANA tool line. These multi-cutters, equipped with laser-sharpened cutting edges and highly durable sealed diamond coatings, handle abrasive materials like nonferrous metals, copper, and even PEEK with remarkable ease.

Cool Precision in Action

The KINGFISHER line is a specialised solution developed for machining challenging materials in the realm of medical technology. It leverages a fresh solid carbide substrate, innovative cooling methods, and a more robust foundational geometry. Combined with state-ofthe-art WAD coating technology, these tools confidently and precisely surmount any challenges. Furthermore, they feature two distinct integrated cooling options that deliver coolant precisely where it's needed: through coolant channels in the shank (SC) and internal cooling (IC), directing coolant directly to the flute.

Reliable Machining of Steels up to 58 HRC, Titanium, Stainless Steel Alloys, and Special Materials

Especially in medical technology, the center cut ensures excellent surface finishes for all QUEEN BEE tools, even in flat areas, in dry as well as wet milling. With adapted flute and micro geometries for good chip removal and quiet cutting, the machining of titanium, stainless steel alloys, and special materials up to 2.200 N/mm² and the pre-milling of soft steel components up to 58 HRC with the highest service life and maximum precision become reality.



Name > Zeltwanger Group

Website > www.zeltwanger.com

Social Media > in □ ☑

Number of Employees > >450

Founded (year) > 1982

Name > Zeltwanger Leak Testing & Automation GmbH

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About Zeltwanger

ZELTWANGER is a market and technology leader in the field of leak testing with air and tracer gases, with a strong focus and years of experience in the medical technology, biopharmaceutical, and electromobility industries. Our customers benefit from our holistic approach. We not only provide them with state-of-the-art, user-friendly, and highly reliable testing technology, along with individually tailored adaptations for their products. We also accompany them through preliminary investigations, offer guidance in selecting the appropriate testing methods, provide training in using the testing technology, as well as comprehensive after-sales services, including certified calibrations and spare parts support.

Ensuring Outstanding Quality

Ensuring the highest quality and reliability in medical devices is critical because it directly impacts human lives. We contribute to this objective with advanced leak testing products, including endoscope leak testers and leak testing solutions for medical single-use systems, which play a vital role in safeguarding the integrity of medical devices and medical equipment.

Leak Testing with Air

While tests with fluids (e.g. bubble test) are still common, pressure decay tests offer a cost-efficient alternative that stands out for its traceability and operator-independent results. Those characteristics are ideal for testing

- Catheters
-) (Bioprocess) bags
- Endoscopes
- Tubing systems
- Lab components

Member of







ZEDcore Measuring Module

The heart of our leak testing devices is the measuring module ZEDcore. It contains the measuring circuit – with choices of different methods such as relative pressure. differential pressure, mass flow, or others. Integratable into each ZELTWANGER device, it offers the utmost precision throughout the whole product family.

Solutions with Tracer Gases

Aspects like the integrity of sterile barriers require a higher sensitivity in some cases. Different methods with helium as a tracer gas offer the highest sensitivity. Possible applications are

- > Bioprocess bags, where it's sometimes necessary to test big volumes for defects of the size of 2 µm or less
- Packaging with a sterile barrier
- Cardiovascular implants

Helium Systems

A process as complex as a helium test requires specified solutions for each application. Therefore, each ZELTWANGER leak test station including a helium test is catered to the customers' needs.

The ZEDfamily

Various demands require different solutions. Devices for one or two measuring circuits, devices for up to eight measuring circuits, or semi-/fully-automated leak test stations – the product family contains the perfect solution for every need, controllable via touch screen, different digi-I/-O solutions, or an external PLC.

Thanks to our extensive experience, our comprehensive knowledge, and our diverse product family, ZELTWANGER is your excellent partner in leak testing.

German Medtech Companies

The register contains cluster members and associated companies of:

FMP: Network Forum MedTech Pharma IVAM: Microtechnology Network **MN1** Cluster Medical Mountains

MTSW: MicroTec Südwest **N/N/** Medical Valley European Metropolitan Region

of Nuremberg

SPECTARIS: German Hightech Industry Association

VDMA: The Mechanical Engineering Industry Associa-

2be die Markenmacher GmbH, Nürnberg (MV) 2E mechatronic GmbH & Co. KG, Kirchheim unter Teck (MM) 2k Produktentwicklung Koentopp + Kargl GbR, München (FMP) 2W Technische Informations GmbH & Co. KG, München (VDMA) 3C-Carbon Composite Company GmbH, Landsberg am Lech (FMP) 3D-LABS GmbH, St. Georgen (MM) 3D-MODEL GmbH, Bad Waldsee (MM)

A.R.C. Laser GmbH, Nürnberg (MV, FMP) AB-CT - Advanced Breast-CT GmbH, Erlangen (MV) ABB AG, Ladenburg (MWST) aberu GmbH, Trossingen (MM) abf diagnostics GmbH, Kranzberg (FMP) ABF-Pharmazie GmbH & Co. KG, Fürth (MV) acad group GmbH, Heilsbronn (MV, FMP, VDMA) ACE Stoßdämpfer GmbH, Langenfeld (VDMA) Acentiss GmbH, Leinfelden-Echterdingen (MM)

Ackermann Instrumente GmbH, Rietheim-Weilheim (MM)

ACMIT GmbH, Wiener Neustadt (FMP) acp systems AG, Ditzingen (MM, MWST)

ACSYS Lasertechnik GmbH, Kornwestheim (VDMA, MM)

Actimage GmbH, Kehl (MM) Active Key GmbH, Pegnitz (MV)

Activoris Medizintechnik GmbH, Gemünden (FMP) Actuator Solutions GmbH, Gunzenhausen (FMP)

ADAPT Localization Services GmbH, Bonn (FMP)

add research - Personalberatung für Medizintechnik, Liederbach am

add'n solutions GmbH & Co. KG, Wurmlingen (MM)

Adelbert Haas GmbH, Trossingen (VDMA)

Admedes GmbH, Pforzheim (MWST)

ADT Angst Drehteile GmbH & Co. KG, Frittlingen (MM)

Advanced Medical Solutions, Winsford (FMP)

ADVANOVA GmbH, Schwaig b. Nürnberg (MV)

ADVITOS GmbH, München (FMP) AEMtec GmbH, Berlin (MM, IVAM)

Aesculap AG, Tuttlingen (MM)

AESCULAP AKADEMIE GmbH, Bochum (SPECTARIS)

aescuvest GmbH, Frankfurt (MV)

AFRA GmbH, Erlangen (MV)

Ageneo Life Science Experts GmbH, München (FMP) AGRODUR Grosalski GmbH & Co. KG, Bad Berleburg (MM) Aicher Präzisionstechnik GmbH & Co. KG, Königsheim (MM)

AimValley B.V., Hilversum (MM, MV)

air-be-c Medizintechnik GmbH, Gera (SPECTARIS)

AIT Austrian Institute of Technology GmbH~H&E Molecular Diagnostics,

Wien (FMP)

AKP GmbH, Freiburg (MM)

AKTORmed GmbH, Neutraubling (FMP)

Albert-Ludwigs-Universität Freiburg - IMTEK, Freiburg (MWST)

Albomed GmbH, Schwarzenbruck (MV)

Albrecht Präzision GmbH & Co. KG. Wernau (VDMA) Alcon® Pharma GmbH, Großostheim (SPECTARIS) Alfred H. Schütte GmbH & Co. KG, Köln (VDMA)

Aligned AG, Zürich (MM)

ALL4NET GmbH, Villingen-Schwenningen (MM) Alleima AB, Mörfelden-Walldorf (IVAM) Allgaier Instrumente GmbH, Frittlingen (MM)

Allied Vision Technologies GmbH, Stadtroda (VDMA)

ALLISTRO GmbH, Frankfurt (MV)

ALLTEC Angewandte Laserlicht Technologie GmbH, Selmsdorf (MM)

ALPO Medizintechnik GmbH, Auerbach (MV, FMP) ALS Automated Lab Solutions GmbH, Jena (SPECTARIS) Altran Deutschland S.A.S. & Co. KG, München (FMP)

AMIPLANT GmbH, Schnaittach (MV)

AMNOTEC International Medical GmbH, Neuhausen o.E. (MM)

AmplexDiagnostics GmbH, Gars Bahnhof (FMP) ams Sensors Germany GmbH, Nürnberg (IVAM)

AMSilk GmbH, Neuried (FMP)

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Angiolutions GmbH, Hannover (FMP)

Antaks GmbH, München (MV)

anteris medical GmbH, Holzkirchen (FMP)

Anton Hipp GmbH, Fridingen an der Donau (MM)

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ARBURG GmbH + Co KG, Loßburg (VDMA, MM)

Arnd Sauter GmbH, Hornberg (MM)

ARTIMED® Medical Consulting GmbH, Kassel (MM)

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ärzte.de MediService GmbH & Co. KG, Nürnberg (MV)

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AS Medizintechnik GmbH, Tuttlingen (MM)

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ASCO Numatics GmbH, Ölbronn-Dürrn (VDMA)

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RSG Bad Kissingen, Rhön-Saale Gründer-~und Innovationszentrum

GmbH & Co. KG, Bad Kissingen (FMP)

RTA Reinraumtechnik Alb GmbH, Trochtelfingen (MM)

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