White Paper

Competences of the IVAM Focus Group "Medical Technology"

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Outline

1. Executive Summary

This White Paper summarizes the competences and experiences of the members of the IVAM Focus Group Medical Technology. The most important ideas that companies have to take into account when they want to develop, produce and sell medical components and products are described in brief chapters. In the end of the paper, the profiles of the member companies are added.

The group was founded 2014 and meets regularly to discuss common issues on new technologies or general aspects of high-tech products for medical applications.

The members of the focus group are mainly small and medium-sized enterprises who produce components or offer production / analytical technologies for medical applications. The member companies are experts in different parts of the value chain and offer their services respectively.

To be successful in the medical market, it is not sufficient to be the world leader in the production of a certain component or in the development of certain production processes. Therefore, it is essential to have partners, e.g.

- experts on regulatory affairs
- experts for reimbursement
- producers of final customer products
- users (doctors, hospitals)
- IT support

The focus group organizes meetings inviting experts from these areas to learn how the members can optimize their development projects and market approach.

The main goal for the partners is to enhance their business. Therefore, regular B2B-meetings will be organized.

The goals of this White Paper are to

- summarize and publish the results of discussions between the focus group members
- give concise answers to some essential questions like regulation or market entry
- describe the competences of the focus group members and their position within the value chain
- identify gaps in the value chain and find new partners who are able to fill them
- facilitate contact between partners all along the value chain

With the help of this paper, potential customers or suppliers should be able to find the right contact for a specific request.

The paper will be updated regularly and can be downloaded on the IVAM website.

2. Introduction to IVAM and its Focus Groups

IVAM Microtechnology Network is an international association with members in the fields of microtechnology, nanotechnology, advanced materials, MEMS and photonics. IVAM supports mainly small and medium-sized companies in bringing innovative technologies and products to market and thus securing advantages in international competition. Since 1995 IVAM has been supporting companies and institutions from all around the world. The central mission of the association is to create synergies and to support its members in exchanging knowledge, initiating joint projects and networking with each other and potential customers.

What does IVAM do?

- IVAM brings innovations to market and create competitive advantages through technology marketing.
- IVAM works on international markets and provide worldwide networking.
- IVAM provides lobbying services for small and medium-sized enterprises in the high-tech industries.

The aim of the IVAM Focus Groups is to enable networking to exchange experience and find the right partner. The general meeting 2014 saw the founding of the first focus groups. The focus groups are to provide a platform for IVAM's members (and interested third parties) to share their experience on current events and activities as well as facilitate coordination of joint activities. On top of this, they are set to directly influence IVAM's activities through their work:

- Which topics should be addressed in IVAM's market research?
- At which trade shows should IVAM organize a joint pavilion?
- In which fields should IVAM assert its political influence?

The medical technology market has experienced a rapid economic upswing in recent years. More than 70% of the IVAM members deal with this issue. The IVAM Focus Group "Medical Technology" serves the professional exchange (introduction of new technologies, components and devices), the discussion of latest trends (e.g. what is the relevance of personalized medicine for component manufacturers?), and the development of common positions, e.g. new registration procedures or planned standardization.

3. Technologies, Services, Value Chain for Medical Products

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by AEMtec

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In preparation:

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a. From Idea to Innovation

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„Imagination is the beginning of creation.
You imagine what you desire,
You will what you imagine, and at last you create what you will."

(George Bernhard Shaw)

This quotation from the famous author shows how the process of innovating starts. But these are only the first steps to generate an innovation. To advance an implemented idea into innovation, there is one specific step needed: It has to penetrate the market.

The word innovation is derivated from the latin verb innovare, which means to renew. There are many different things which can be renewed or invented. Related to this, innovations are varied: Innovation of products and service, procedure and process, management and organisation innovation, innovation of business model, design innovation, social innovation and innovation of systems. Generating innovations require a couple of features.

First there has to be motivation. Motivation can be intrinsic or extrinsic, per definition it is the sum of motives which leads to willingness for action. Second is creativity, which is the feature to imagine and create physical or unphysical values. The IVAM association can bring motivated people from different companies together to raise creativity, like Albert Einstein said: "Creativity is contagious, pass it on". People with different educational background from different lines of business meet and swap ideas while working on different topics, all to target new ideas for our branch. Network will make it easy to find the companies which can help you to create new ideas or inventions. Finding and selecting the one idea between many others, that is a very tough process and sometimes when you innovate, you make mistakes. It is best to admit them quickly, and get on with improving your other innovations.

And then there is only one step ahead, which your business has to do, to generate an innovation: Penetrating the market. This, the implementation of innovation to the market is not easy, but this is the purpose of business. The network of the IVAM can and will help to find the ideas which generate innovations to keep the technological hegemonies of our branch for the future.

And keep in mind:

"Innovation distinguishes between a leader and a follower." (Steve Jobs)

b. Finding the Right Partners

Matthias Lorenz
AEMtec GmbH
Berlin, Germany

For many OEMs, a crucial decision in taking a medical device from concept to market is selecting the best electronics manufacturing service. Matthias Lorenz, Business Development Manager MedTech at AEMtec GmbH, Berlin guides us through the process of making appropriate outsourcing decisions for microelectronic products commonly used in different medical devices.

Increasing market pressure might convince medical device companies to focus on certain segments and core competences and then decide to offload the business that does not fit into that strategy. Contract manufacturers as well as electronic manufacturing service suppliers have played a significant role in the medical device industry for decades, and that role will continue to expand tremendously in the years to come. There are many benefits of offloading this business including:

- Lower costs
- Reduced capital expenditures
- Options for complex manufacturing processes
- Benefit from a brought network of partners and knowledge
- Freedom from day-to-day concerns
- Greater focus on company´s core technology
- Lower overhead

There is not much of a difference whether the customer operates in the field of prophylaxis, diagnostics, treatment, rehabilitation or even prevention. The process of selecting a partner for outsourcing development and production tasks always follows the subsequent steps and rules. These are:

Market analysis of potential partners

The partner needs to offer a comprehensive and extensive basic knowledge in the requested technologies. If possible, the partner should also have reference projects with similarities to yours that demonstrate their capabilities, but that´s not a must. It´s more important that the potential partner offers an all-encompassing quality management system covering at least the most common standards, e.g. ISO 13485, EN 60601 and ISO 14971. Prescreen potential companies by conducting your own survey and make a 1st preliminary rating which will be used for your ongoing supplier assessment.

Creating a short list

Screen the supplier on the phone. Don´t reveal too many details about your project. Be prepared to listen. In this most important step for supplier selection you can separate the wheat from the chaff. This means that only suppliers who listen carefully to what you have explained with respect to the project, who ask the right questions and who transfer the right information to you and your team are the ones you may put onto your short list.

Questionnaire and on-site assessment

Both the questionnaire and assessment techniques are used for the selection of potential candidates. They are used to help determine which outsourcing partners have the potential to be promoted into the project. The assessment team should consist of employees from all divisions which are involved in the selected project, at least from the engineering, procurement and quality areas. Based on past experiences, assessment teams usually slip up by rating and scoring potential partners through using a “dummy project”. Of course – this procedure can be used for market research. But it will hinder your internal progress. Discussing assumptions, spending time for tasks which have to be repeated for the “real project” is a waste of time and will lower your perception as a reliable partner. Keep in mind, the potential partner also spends time and money to read and to answer your questionnaire or request for proposal. Therefore you have to be prepared to poll for the following elements:

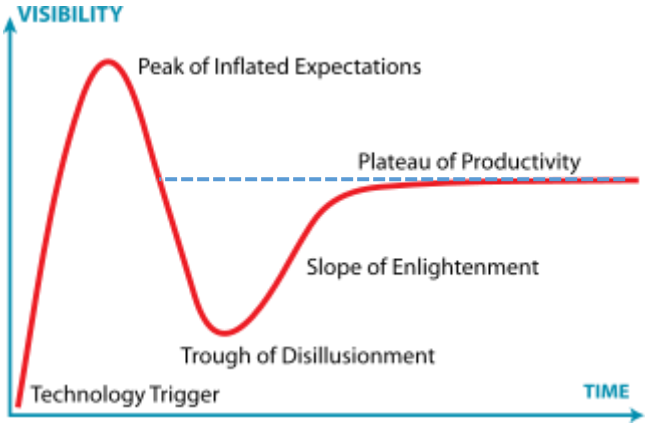
- Background and objectives including all available project information
- Scope of work, scope of service consisting of schedule, quantities and life cycle
- Working assumptions as well as responsibilities
- List of materials and/or equipment which has to be provided to the partner
- Methods and standards
- Deliverables including acceptance and reject criteria’s

Selection

Even if the decision to outsource is clear, the selection of two or three potential partners who will receive your request for quotation is the most crucial and important decision. Take your time. No need to hurry. But there is also no need to delay the selection process. The record of compliance with regulatory, safety, technology and production standards, as well as experience, capability and capacity for producing your product as mentioned before, are good indicators that the partner will be able to expeditiously bring your product to market and maintain supply of the product over time.

Confidence

The above mentioned hard facts are only the tip of an iceberg. From my point of view one of the most misunderstood but essential decisions to make during a supplier selection process relates to confidence. Confidence is a soft fact. Confidence is something nobody is able to explain and to justify. Confidence is a gut feeling which is given congenitally. Nevertheless confidence follows the Gartner graphic which is also well known as the “Hype Cycle”. Usually this graphic is used to explain how and why things went different than expected. But you can use this graphic for the supplier selection process, too.



The technology trigger is where a breakthrough or a new idea first begins to interest. This covers both your own project as well as the search for potential partners. As a last resort this can be the point of no return based on incorrect interpretations or incomplete information or even wrong expectations

The peak of inflated expectations is the phase where a concept, a technology or even a completed supplier selection process is seen as the solution to all ills. At this point, the process is pushed to a limit, with some successes and plenty of failures. There is a lot of hype during this phase, as its name implies.

Once reality sets in, the program enters the trough of disillusionment. In this phase, there isn´t as much interest and there´s possibly more criticism than praise. But why is that? Has the assessment team done a bad job? Has the supplier promised more than he is capable to do? For sure this will lead into a melting pot with no loophole. To get rid of this it is mandatory that during the assessment phase the scope of work needs to be conveyed without any secrets. Companies are wrong when thinking that it is an advantage to withhold information. This leads into delays, costs, and dissatisfaction. And – you have to undertake a great deal of effort to achieve the slope of Enlightenment, during which the technology begins to mature and partners continue to experiment and innovate.

When real-world applications appear and are accepted and the value proposition gains traction, the relationship between the customer and the selected supplier hits the plateau of productivity, where more widespread adoption occurs. Once the partnership reaches this level, it has become established and viable.

Conclusion

Choosing the right partner is critical for the success of the project. Everyone has to spend the time required to make a good decision: gleaning as much tangible and nontangible information on all your options as possible and then objectively comparing them. You should have an idea about how to evaluate and weigh nontangible factors into the decision and once you have made your choice, manage partnerships according to those criteria. Although everyone has preferred methods for supplier selection, my suggestion works well for both parties.

c. Developing Unique Selling Propositions

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Small and medium sized businesses (SMBs) have a strong interest in securing their future with a unique position on the market. Offering good, fast, fair priced, etc. services is seen as standard and the scale factor works in advantage of larger corporations. In the field of medical technology regulations and lengthy admission procedures further benefit the established institutions.

In our experience, SMBs often lack R&D capabilities for the kind of innovative research, which will not pay off in near future, but may result in the specific feature, that enables the company to keep up with the movement of the field. Ironically, there may exist a specialized company A, who could offer the distinctive feature complementary for company B, but both sides do not know that. Company A cannot advert all possible uses for their technique – or even see all applications, for that matter. Company B does not want to make their plan (and their problem) public, of course.

Medical technology may be viewed as a heterogeneous field, with many businesses basing – or having core expertise – in one subfield, such as chemical engineering, electrical engineering, and computer science/mechanical engineering. The meta-topics nanotechnology and information connection (“internet of things”) expand the space of cooperation possibilities furthermore. For example, now the synthesis of imagery, simulation and robotics seems to reach the threshold to create medical virtual reality applications. These have already changed surgery with image-guided or remote-controlled systems.

The question arises, how to find the right partner to develop with – or to develop for – solutions in terms of techniques and applications. Also the search for suppliers in a very specific field is demanding. While the Internet offers more or less sophisticated websites for information, it cannot provide much of the most necessary resource for initiating cooperation: trust. To develop outstanding abilities more than technical expertise is needed. Before even starting a common basis for trust has to be found. This is where Nanobay comes into place and connects the diverse agents of the market and the networks of different fields. For example, our structured knowledge-system allows to research for the laboratory providing a specific substance. If a company sees a product or substance phasing out of use (e.g. nano silver) and wants to get familiar with possible substitutes, then Nanobay offers connections to several providers of exemplars. Also consulting about candidates for non-specific collaboration is a common request by our customers. Furthermore we anticipate new developments in the very competitive nanotechnology market and showcase concepts for future products.

d. Total Cost of Ownership - TCO Approach

Matthias Lorenz
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Berlin, Germany

Total cost of ownership (TCO) is the purchase price of an asset plus the costs of operation. When choosing among alternatives in a purchasing decision, buyers should look not just at an item's short-term price, which is its purchase price, but also at its long-term price, which is its total cost of ownership. The item with the lower total cost of ownership is the better value in the long run.

BREAKING DOWN 'Total Cost Of Ownership - TCO'

Both companies and individuals consider total cost of ownership when purchasing assets and making investments in capital projects. While these costs are most often itemized separately on a company's financial statements, comprehensive analysis of the cost of ownership is a common practice for business dealings. In a corporate business decision, companies use the total cost of ownership over the long term as a framework for analyzing business deals. This analysis includes the initial purchase price as well as all of the direct and indirect expenses. While the direct expenses can be easily reported, companies most often seek to analyze all of the potential indirect expenses that can be of significant influence in deciding on whether to complete a purchase.

Business Investment Example

An example of a business investment that requires thorough analysis of the total cost of ownership is an investment in a new computer system. The computer system has an initial purchase price. Additional costs of the computer system also often include new software, installation, transition costs, employee training, security costs, disaster recovery planning, ongoing support and future upgrades. Using these costs as a guide, the company compares the advantages and disadvantages to purchasing the computer system as well as its overall benefit to the company for the long term.

On a smaller scale, individuals also use the total cost of ownership when making purchasing decisions. While total cost of ownership can be overlooked, its analysis is essential in preventing unnecessary future losses that can arise from focusing only on the immediate direct costs of a purchase.

e. Prototyping in the Development Process

Services of the members of the Focus Group for Medical Technology (using 3D MID–Technology as an example)

Stephan Huttenlocher
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The company of the IVAM Focus Group for Medical Technology offers services for the entire product development process and for mass production. From the sector of plastics technology, an innovative process is used as an example to demonstrate the possibility of producing MID prototypes. The goal of the "MID" technology (Mechatronic Integrated Devices) is the miniaturisation of the components and systems of microsystems technology and the functional integration when reducing the number of parts at the same time.

The MID process currently used most frequently is Laser Direct Structuring. LDS describes the process which makes it possible to produce layout structures on three-dimensional plastic injection-moulded parts, which are then converted into 3D circuit carriers in later process steps. The LDS process relies on plastics with a special endowment of metal cores which the laser releases during the structuring, so that the metal atoms can attach themselves during the subsequent metallisation. The most popular LDS-MID application is the smartphone antenna. Other exciting applications can be found in the new development or redesign products used for medical-technology. Examples of these include flow sensors, LED and OLED elements, or hearing devices. Product configurations can be used in many branches such as the IT sector to assemble and acquire customised products. In contrast, the implementation of variants in the production of functional LDS-MID prototypes has previously always been connected with high additional costs. This was primarily due to the high financial expenditure for the prototype injection-moulding tools and the various inserts required for the variants. Any design changes made necessary by testing were generally also again connected with high costs.

A process of prototype production offered by a company of the expert group now makes it possible to quickly and inexpensively manufacture production-ready LDS-MID prototypes. The production of similar products, which differ only in detail, is thus possible at minimal cost.

The substrates must no longer be injection moulded, but are rather produced from original materials (semi-finished parts) on a micro-milling centre.

This is followed by laser structuring and the metallisation for producing the conductor paths. Design changes for both processes require solely software adaptations. The same applies if SMD assembly is required following chemical metallisation. Thus no product-specific tools are needed for the entire prototyping process.

Examples of LDS-MID prototype variant management include LED light elements produced by the company. Originating from a development which was specially implemented for one application, it is now quickly and easily possible to make modifications for other applications and industries. Various versions of the socket were realised in the present case. It was already possible in the prototype phase to quickly and inexpensively produce various functional models and to test their function. Any required design changes could be quickly and easily integrated.

Image: Fast, inexpensive production of fully functional prototypes from original materials using MID technology as an example (LaserDirectStructuring)

f. From Prototype to Serial / Mass Production

Ingolf Reischel
JENOPTIK Optical Systems GmbH
Jena, Germany

From your idea to the complete system solution

“As a strategic partnership network, we enable our customers' success by developing customized system solutions that inspire global markets through innovation, performance and service."

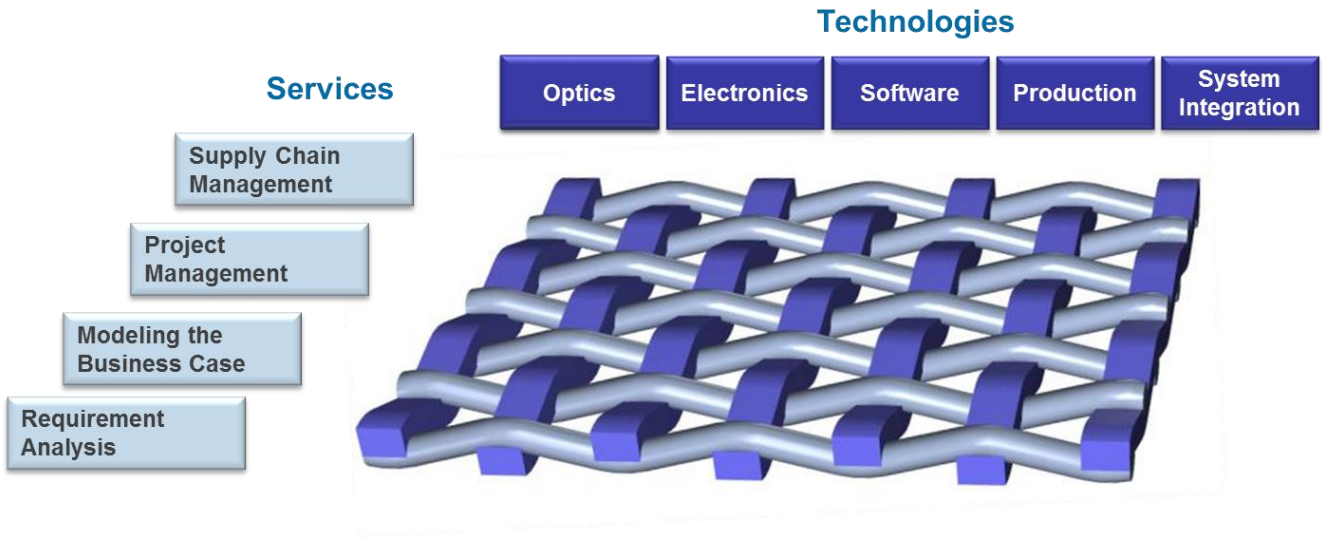
The IVAM network realizes all steps in the complete technology chain under one roof. All product developments and product realizations are running under the conditions for medical devices independent if it’s a single component, a submodule for a complete device, as a contract manufacturing partner or a legal manufacturer.

Beside the technological competencies the service aspects become more and more important in a project partnership to be a strategic partner for the final customer.

The realizations start with a low quantity for prototypes up to a complete mass production according to the customer needs. Having in mind that just from the first product idea all necessary regulative requirements are fulfilled with a focus to a stable and reliable production.

Other aspects are:

- Time to Market (TtM), Time to Costs (TtC)
- Complete technology base
- Stable and reliable processes in accordance with the medical device regulations
- Excellent quality, safe and effective products for medical application



g. Serial Production

Izumi Nakamura
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Osaka, Japan

Lot size analysis

You categorize the parts by the lot size per order. In order to determine whether the lot size is large or small, you make standard by calculating the average ordered price. When it is above the standard, it is a large lot and when below it is a small lot. Economic Lot Size (ELS) is the volume where the total of ordering cost and inventory maintenance cost will be minimum.

For example, when the lot size is larger, the average inventory standard increases, which will also increase the inventory maintenance cost. However, logistic cost and administration cost can be divided by many parts, which per unit is not so much.

On the other hand, if you have smaller lot size, average inventory standard decreases, which will also decrease inventory maintenance cost. The ordering cost per unit will increase in this case.

Capacity planning

Capacity planning is the act of establishing, measuring and adjusting limits or levels of its manufacturing capacity. Effective capacity is the maximum amount of production that a company can complete in a given period of time considering material handling, quality problems and other factors. The goal of capacity planning is to minimize discrepancy between the capacity of a factory or a machine and the demand of customers.

Risk analysis

Risk analysis is a sequence of process to identify risk or hazard in a factory, to estimate the risks, to make priorities, and to countermeasure in order to reduce the risks. Manufacturing companies should take appropriate countermeasure based on the risk analysis. Especially for medical device/equipment manufacturers, it is very important not to have any defect but also when a problem occurs, safety must be maintained.

Employee training

For the new graduates, it is important to give them basic training where they understand what company and the appointed department does and how various systems in the workplace operate. Small quiz to check the level of the understanding is recommended.

For managerial positions, continuous training to improve the knowledge as managers, the ability to make correct judgement, how to supervise staff, leadership skill etc. are required.

It is necessary to have training on quality assurance, risk management, new technology, communication skill as well as presentation skill, depending of the position of the employee.

Process accompanying quality assurance

In the manufacturing process, there is quality control flowchart. This is a flowchart showing control characteristics and control method in each process from material to shipment of the final product. That means, it shows which quality characteristics is controlled by who, when and how in order to guarantee quality in the factory.

The purpose of this chart is:

- To thoroughly check potential problems in each process.
- To reflect the “Kaizen” activity and result of detection of abnormality and troubleshooting.
- To explain to the customer the situation of the quality control
- To ensure quality control activities are implemented. This prevents defects.
- To record the result of quality improvement and change management process.

Demand deviation

In order not to be affected by demand deviation of the customer or the market, if possible, it is advisable to make diversification of the risk by manufacturing for various industries. For example, we have a wide range of industries from medical device, to automotive, to jewelry and eyewear, to name a few.

Material logistic

Main function of material logistics is to pack, store and transport materials as well as to process the information of the logistics.

It is important to source the material not from one supplier and one logistics company but from at least two or three suppliers and logistics companies in case some natural disaster, major accident or strike occurs.

h. Placing Medical Products in the Market

Corinna Weber
Sensor Basierte Neuronal Adaptive Prothetik GmbH (SNAP)
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Medical devices may be commercialized or put into operation only if they bear a CE marking. In order to receive the CE marking, the product must comply with the essential safety and performance requirements of the known directives and the prescribed conformity assessment procedure has to be carried out.

This formal legality for placing a medical device on the market is the sole responsibility of the manufacturer. As soon as the product idea arises, the manufacturer must take due account of the medical product legislation. This requires a proper documentation of each step from the product idea to the serial product. The basic requirements are laid down in Directives 90/385/EEC (Active Implantable Medical Devices), 98/79/EC (In Vitro Diagnostic Medical Devices) and 93/42/EEC (Medical Devices Directive).

The potential risk of the product determines the conformity assessment procedure and whether a Notified Body (certification body) is to be involved. Depending on the risk, medical devices are divided into four classes (I, IIa, IIb, III, Directive 93/42/EEC). Risk assessment, risk minimization procedures, conformity assessment procedures and a risk / benefit analysis must be carried out.

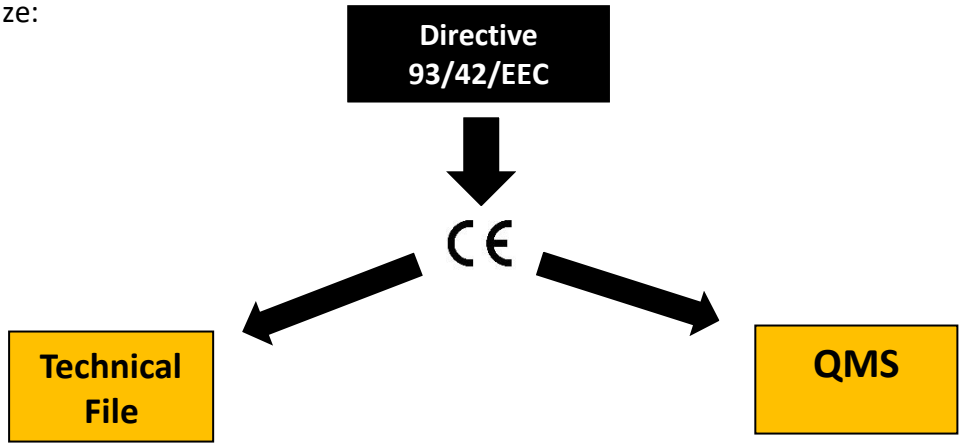
Which conformity assessment procedures are to be carried out depends on the potential risk of the product. As the risk indicators are not differentiated any further, Directive 93/42/EEC provides for a differentiation of products into four classes (I, IIa, IIb, III). The Directive on Medical Products describes the conformity assessment procedure and its implementation. All medical devices which do not fall into risk class I must receive a conformity assessment with the participation of a Notified Body. The certification authority will carry out the assessment and then create the required certificate. The notified body may be freely selected by the manufacturer.

i. Guide for Medical Device Subcontractors

Florent Guyon
Statice
Besançon, France

Introduction

To sell a medical device on the European market, a legal manufacturer has to obtain the CE mark. He has to follow the requirements precised in the Directive 93/42/EEC
To summarize:



General Guidance

- **STED** : Summary Technical Documentation GHTF/SG1/N063 : 2011
- **Classification** : GHTF/SG1/N77 :2012 & MEDDEV 2.4/1 rev 9
- **Safety and performance** of medical devices : GHTF /SG1/N68 : 2012

EN ISO 13485 : 2012

- ISO 19011 : 2012 : Audit
- ISO 10012 : 2003 : measurement management systems
- ISO 2859-1 : sampling procedures for inspection

Risk Analysis

- EN ISO 14971 : 2012
- GHTF SG3 N15 R8 : 2005

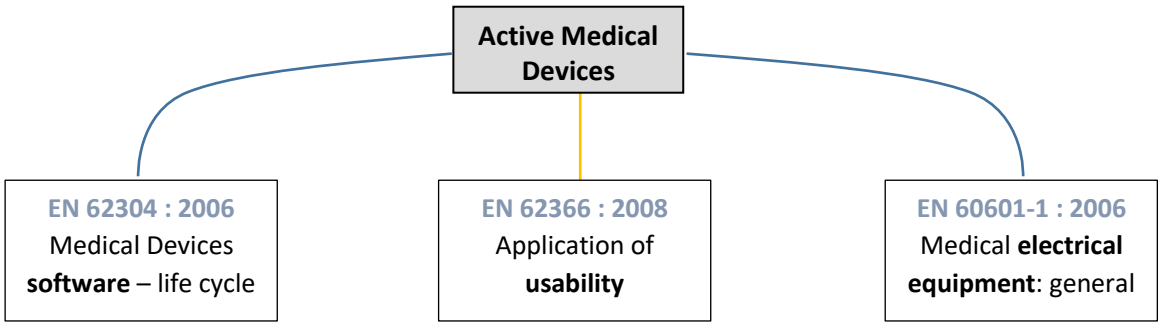
Clinical evaluation

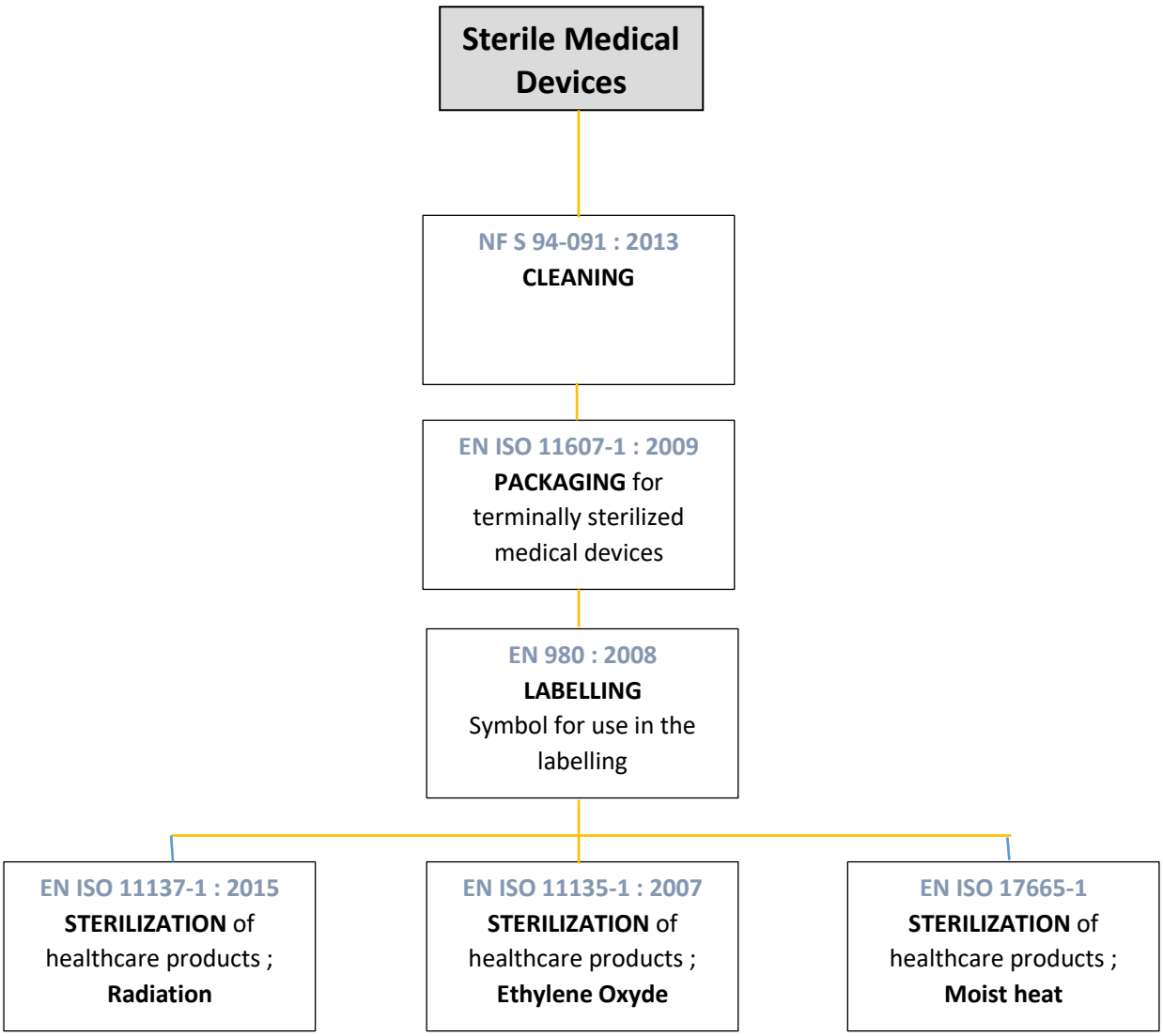
- EN ISO 14155 : 2011 : clinical investigation
- MEDDEV 2.7/1 rev.4 : clinical evaluation

Biological evaluation

- EN ISO 10993-1 : 2009 Biological evaluation

The key standards





4. Member Profiles

Further Profiles will be added soon.

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Position in supply chain

Applied Research & Key Experiment	Industrial Research & Development, Prototype	Production, 1st Series	Clinical Tests & Studies	Registration, Approvals & Reimburse-ment	Serial Production
	x	x			x

Activities / products / services

2E is partner in the development, design and manufacture of customized solutions. We also offer in-house developed products, e.g. inclination sensors. Our technological core competences include high-precision injection-moulded plastic parts with inserts, microfluidic parts, MID technology (Mechatronic Integrated Devices) including packaging as well as the assembly of complete systems.

Technologies

- MID technology
- Housing technology
- Sensor technology
- High-volume production
-

Markets

- Medical
- Industrial electronic
- Automation Industry
- Automotive

Why use our technology / services?

Our technologies, e.g. the MID-technology, enable our customers to manage key challenges like miniaturization of products or integration of various functions.

High sophisticated products like inclination sensors, microliter pumps, LED elements or flow sensors improve the performance of products and systems.

Customers like KaVo, Novuqare, Leica, BienAir, Sirona and many more trust in our competences and innovation.

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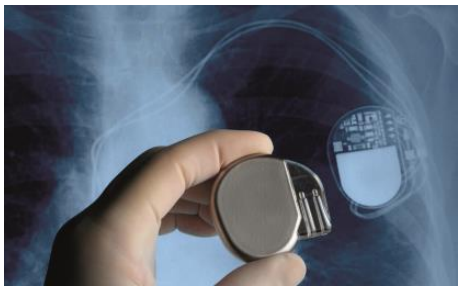

Position in supply chain

Applied Research & Key Experiment	Industrial Research & Development, Prototype	Production, 1st Series	Clinical Tests & Studies	Registration, Approvals & Reimburse-ment	Serial Production
	X	X			X

Activities / products / services

Next Level Microelectronic and Optoelectronic Assemblies for Medical Devices (Class I – III), such as Professional Wearables, Handhelds, Imaging and Acoustic Systems, Laboratory Diagnostic and Active Implants.

Technologies

- Wafer Back-End (UBM, SBA)
- Die- and Wire Bonding
- Flip Chip Bonding
- SMT
- Assembly of Optical Components

Markets

- Medical Technology
- Data- Telecommunication
- Industry & Automation
- Semiconductor
- Transportation (Automotive, Aerospace)

Why use our technology / services?

AEMtec produces prototypes through to high quantity serial production in cleanroom environment up to Class 100. We also place great emphasis on process development work. Diverse concept developments, exact specifications, feasibility and systematic risk analysis (FMEA) form the basis for safe and reliable results.
By offering a high standard of technology equipment (UBM, SBA, Dicing, COB, FC, SMT, Box-Build) and process services, our Customers benefit from reduced supply chain time, risk and cost. Assuming responsibility for the entire production chain and full product quality enables potential errors to be more easily identified and eliminated and production processes to be adjusted and improved accordingly. AEMtec is a member of exceet Group S.E. with excellent technology competence in the area of intelligent electronics and safety technology through to complete safety solutions.

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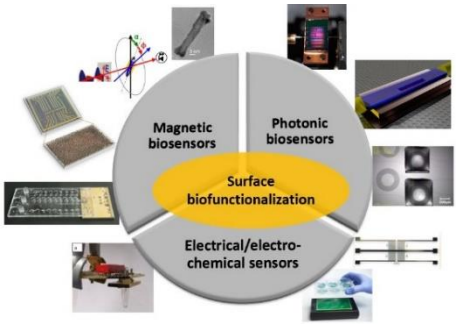

Position in supply chain (Please remove X where not applicable)

Applied Research & Key Experiment	Industrial Research & Development, Prototype	Production, 1st Series	Clinical Tests & Studies	Registration, Approvals & Reimburse-ment	Serial Production
X	X				

Activities / products / services

The applied research focus of our group is the development of high sensitive medical diagnostic biosensors and their system integration for Point-of-Care (PoC) applications (www.ait.ac.at/en/research-fields/point-of-care-diagnostics-biosensors/).

Technologies

- Electrical/Electrochemical biosensors
- Magnetic biosensors
- Photonic biosensors
- Surface biofunctionalization
- Microfluidics and system integration

Markets

- Life science
- Human diagnostics
- Veterinary diagnostics
- Lifestyle

Why use our technology / services?

AIT's Molecular Diagnostics specialists are committed to develop highly sensitive biosensors for analyzing liquids, such as serum, urine or saliva, using electrochemical, magnetic and photonic sensors. Furthermore, AIT has strong expertise in the integration of biomarkers, sensors, microfluidics, reactors, thermal management and readout electronics for such systems. As example, here are some of our major reference projects:

- DIAGORAS – Point-of-Care device for rapid and accurate prescription of personalized treatment for respiratory and oral infections (www.diagoras.eu).
- NaCoS - Fully printed biosensors based on nanocomposite biofunctionalisation (www.nacos.researchproject.at).
- OCTCHIP – Ophtalmic optical coherence tomography on a Chip (www.octchip.researchproject.at).
- PIONIER - Paper-based disposable electrochemical system for PoC diagnostics (www.projekt-pionier.com).
- PLASMOfab - Surface biofunctionalisation and microfluidic solutions for plasmonic biosensors (www.plasmofab.eu).

Fraunhofer
IBMT

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Micro Implant for long-term intracranial pressure monitoring.

Position in supply chain

X X

Activities / products / services

The Fraunhofer IBMT offers concept, design, development and prototyping services for active implants in a wide range of applications.

Technologies

- Wireless powering and data transfer (RF, RFID, infrared and ultrasound).
- Miniaturized electrodes, sensors and actuators.
- Miniaturization by intelligent electronic design.
- Firmware/software development and signal processing.
- System aspects, encapsulation and testing.

Markets

- Dental implants for monitoring, electrostimulation and oral drug delivery purposes.
- Implants for remote-controlled hydrocephalus treatment.
- Implants for wireless monitoring of intracranial pressure.
- Implants for electrostimulation purposes.
- Theranostic implants.

Why use our technology / services?

The department Biomedical Microsystems has more than 15 years of experience in the business of active implants. We gained our knowledge in publicly-funded and industry-funded projects covering all aspects of the innovation chain from concept and feasibility studies to product design and development as well as prototyping and in vitro biocompatibility testing. We are used to dealing with challenges like miniaturization, efficient and space-saving powering, wireless power and data transfer between external and implanted modules as well as encapsulation and housing.

Fraunhofer ILT

Fraunhofer-Institute for Laser Technology – ILT

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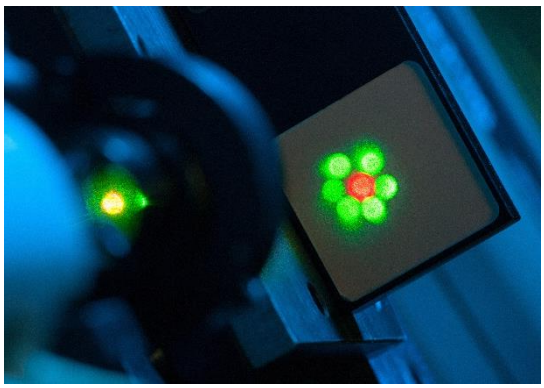

Position in supply chain

X

Activities / products / services

ILT performs contract research on laser sources and components, precision laser machining, and biomedical applications. The scope of work range from proof of principle to detailed technological studies and setup of prototype tools.

Technologies

- Laser ablation, laser cutting and welding
- Process control
- Optics and fiber delivery
- Biomedical / therapeutic laser applications
- Biofabrication, 3D printing

Markets

- Medical products
- Medical lasers
- Packaging plastics, metal, glass
- Applied R&D

Why use our technology / services?

ILT provides comprehensive technological expertise in laser sources, components and process control. Customers benefit from:

- Development of new laser beam sources and components, precise laser based metrology, testing technology and industrial laser processes
- Expertise in process control, modelling and simulation as well as in the entire system technology.
- Full coverage from proof-of-principle to prototype setups, production of samplings

Fraunhofer ISIT

Fraunhofer Institute for Silicon Technology (ISIT)

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Position in supply chain

Applied Research & Key Experiment	Industrial Research & Development, Prototype	Production, 1st Series	Clinical Tests & Studies	Registration, Approvals & Reimburse-ment	Serial Production
X	X	X			

Activities / products / services

- Sensitive, fast and robust Point-of-Care-Diagnostics using electrical array biochips in a portable platform.
- Biochip technology and biosensor system engineering for different analytical applications.

Technologies

- Electrical Array-Biochips
- Enzyme Sensors for Continuous Monitoring
- Multiparametric Sensor Systems
- Biosensor Technology
- Microelectronics and Microsystem Technologies

Markets

- Point-of-Care-Diagnostics
- Immunoassays
- Infectious disease detection
- Healthcare & Life Science Applications
- Therapy monitoring

Why use our technology?

The electrical biochip technology is very robust by avoiding optical parts. The technology is patented and the disposable biochips could be manufactured in ISIT´s clean room environment from research prototype level up to industrial scale.

The platform characteristics enable the adaption of nearly any immunological based ELISA to our biochip technology – to realize sensitive and time-saving analysis.

A main field of application is the detection of infectious diseases. In this regards the analysis of Hepatitis-C (HCV) and Malaria infections could be demonstrated successfully. Further sample applications are the detection of biomarkers like C-reactive protein (CRP), Interleukin-6 (IL-6) and Prostate-specific Antigen (PSA).

Hahn Schickard

Visions to Products

Hahn-Schickard

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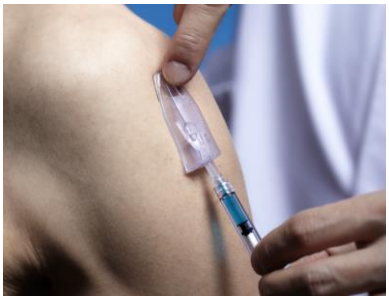

Position in supply chain

Applied Research & Key Experiment	Industrial Research & Development, Prototype	Production, 1st Series	Clinical Tests & Studies	Registration, Approvals & Reimburse-ment	Serial Production
X	X	X			

Activities / products / services

Hahn-Schickard develops intelligent products by applying microsystem technologies: from the initial idea or concept up to production – across all industrial sectors.

Technologies

- Silicon MEMS technologies
- Polymer and molding technologies
- Structuring of surfaces + MID
- Micro assembly + packaging
- Printing techniques

Markets

- Life sciences + medical technology
- Mobility + movement
- Sustainability, energy, and environment
- Internet of Things

Why use our technology / services?

Microsystem technologies enable innovative solutions for improving your medical and health-related products. Possible applications are numerous and diverse, e.g.

- intelligent intradermal and intraoral medication dosing systems,
- mobile diagnostic devices for rapid on-site analysis of infectious diseases,
- assistive sensor systems for medical rehabilitation or respiratory applications,
- improvement of medical instruments.

In our three foundries in Southern Germany for

- MEMS (Villingen-Schwenningen)
- lab-on-a-chip systems (Freiburg)
- micro assembly + packaging (Stuttgart)

We develop and validate your prototype up to serial-production quality. This enables you to benefit from our manufacturing expertise bridging the gap between first functional model and serial production. Hence, costly investments can be reduced and development risks are minimized.

Reference project:
In 2017, the dermaject® intradermal injection device (see image) developed together with the Hahn-Schickard spin-off Verapido Medical GmbH received CE-certification.

Hochschule Niederrhein
University of Applied Sciences

FTB
Forschungsinstitut für Textil und Bekleidung
Research Institute for Textile and Clothing

Hochschule Niederrhein – University of Applied Sciences Research Institute for Textile and Clothing (FTB)

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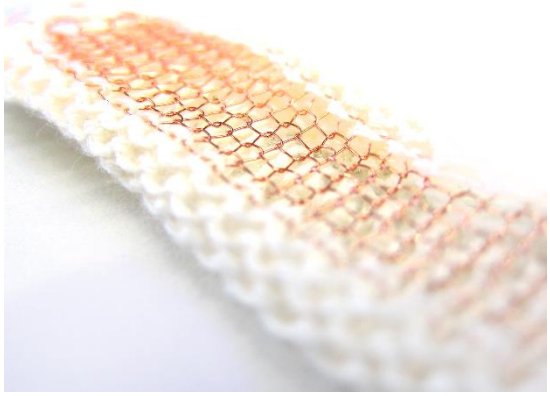

Position in supply chain

Applied Research & Key Experiment	Industrial Research & Development, Prototype	Production, 1st Series	Clinical Tests & Studies	Registration, Approvals & Reimburse-ment	Serial Production
X	X	X			

Activities / products / services

The Research Institute provides research and development services along the complete textile production chain, from yarn spinning to garments.
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Technologies

- surface functionalization
- digital printing
- technical embroidery
- weaving/knitting/spinning
- smart textiles & wearables

Markets

- medical textiles
- industrial textiles
- clothing / PSA
- composites
- automotive

Why use our technology / services?

Our expertise in textile functionalization spans from introducing electronic functions in textiles, over adjusting the polarity of textile surfaces, digital functionalization (i.e. conductive inks), different coating technologies, textile finishing to 3D-printing.

We also provide the production of textile materials for example by spinning, weaving, knitting, braiding, and technical embroidery.

We conduct different activities in direct industrial cooperations as well as public research projects. Bachelor and Master thesis can also be prepared together with a company.

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Position in supply chain

Applied Research & Key Experiment	Industrial Research & Development, Prototype	Production, 1st Series	Clinical Tests & Studies	Registration, Approvals & Reimburse-ment	Serial Production
	X	X	X		X

Activities / products / services

Product development and contract manufacturing for medical devices and subsystems.

Technologies

- Product design
- Contract manufacturing
- Mechatronic assembly
- Precision mechanics
- Supply chain management

Markets

- Medical technology
- Analytical, bio- and laboratory technology
- Photonics-optics

Why use our technology / services?

We are your certified service provider for development and serial production of mechatronic devices.
Jueke offer customers a range of production and assembly capabilities as well as our expertise in the development and enhancement of their products in terms of technology and economic efficiency. We also take over the complete logistics management of projects. Our processes are certified according to ISO 9001 and EN ISO 13485.

We support OEM manufacturers as strategic partner over the complete product life cycle. In addition to development and design, our strength contain the manufacturing and assembly of prototypes, individual systems and series production. We are a one-stop service provider with the capacity to support the entire process from development through to series production. This is one of our most important unique selling points. Close support from our highly qualified project engineers and the use of modern production methods and resources are of particular importance for our customers.

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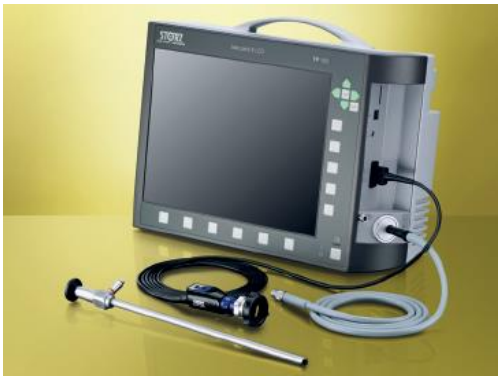

Position in supply chain

Applied Research & Key Experiment	Industrial Research & Development, Prototype	Production, 1st Series	Clinical Tests & Studies	Registration, Approvals & Reimburse-ment	Serial Production
X	X	X	X	X	X

Activities / products / services

Global manufacturer and distributor of endoscopes, medical instruments, and devices.

Technologies

- Optics
- Fine Mechanics
- Electronics
- Software

Markets

- Medical endoscopes
- Cameras, light sources and documentation
- Operating Room OR1™
- Veterinary endoscopes
- Industrial endoscopes

Why use our technology / services?

As a system supplier, the company combines its expertise in endoscopy with software solutions to achieve integration in the operating room and to support clinical process and resource management.

- Full spectrum of endoscopic system technology.
- Extensive and highly differentiated range of endoscopes and instruments in the all fields of medicine.
- Fully integrated Operating Room, centrally monitored and controlled, in which surgical processes and routine work are simultaneously streamlined and simplified.
- Endoscopy is also an indispensable tool in industry. Rapid, inexpensive and objective information about the interior condition of an object without the need for time-consuming disassembly

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Position in supply chain (Please remove X where not applicable)

X X X

Activities / products / services

Research, analysis and writing services for health IT and medical technology companies.

Markets

- Health IT
- Medical Technology
- E-Health
- Privacy & Security

Why use our technology / services?

Do you need to communicate advantages and characteristics of your technological solutions to B2B and/or B2C audiences?
We are an interdisciplinary medical and IT team with a portfolio of articles in well-known industry publications as well as specialist books. We will assist you with literature research and analysis services as well as writing, ghostwriting and editing.

For detailed references, see www.serapion.de/portfolio and our blog at www.serapion.de/blog.

SONOTEC
ULTRASONIC SOLUTIONS

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Position in supply chain (Please remove X where not applicable)

Applied Research & Key Experiment	Industrial Research & Development, Prototype	Production, 1st Series	Clinical Tests & Studies	Registration, Approvals & Reimburse-ment	Serial Production
X	X	X	X		X

Activities / products / services

SONOTEC is an internationally operating technology venture, established on the market as a provider of specific solutions using ultrasonic measurement technologies. We develop, produce and distribute ultrasonic sensors for various applications.

Technologies

- Ultrasonic measurement technologies for flow rate measurement, air bubble detection and blood detection

Markets

- medical devices
- bioprocessing industry
- pharmaceutical industry

Why use our technology / services?

- Compact design with integrated electronics; non-invasive clamp-on solutions for a wide range of tubing sizes, materials and colors; and many more…
- Plug & Play device for easy implementation; highest hygienic standards; eliminates the risk of contamination of the media; and many more…
- Dialysis machines; Heart-lung and ECMO machines; Mixing, dispensing and dosing systems; Blood separators and chromatographers; and many more…

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Position in supply chain

Applied Research & Key Experiment	Industrial Research & Development, Prototype	Production, 1st Series	Clinical Tests & Studies	Registration, Approvals & Reimburse-ment	Serial Production
X	X	X			X

Activities / products / services

We provide contract R&D and contract Manufacturing of medical devices. We specialize in the transformation of silicone and of bioresorbable polymers. We also provide innovative catheters and electro-medical equipment.

Technologies

- Bioresorbable implants
- Long term implants
- Active medical devices
- Advanced intraluminal technologies
- IVD devices

Why use our technology / services?

Please describe in a short text the advantages of your product or technology and in what way users might benefit from applying it, e.g.:

In our R&D department work 25 engineers, doctors and technicians, all with a strong background in medical devices development. They have skills in biomaterials transformation and mechatronics. We work in compliance with regulations and standards (ISO 13485). We have a mechanical workshop in house which makes us very flexible and quick in response to customers. Every customer is unique, we are used to work on bespoke solutions. We have a design transfer department with 5 engineers and technicians working exclusively on the transfer of developments to production. The manufacturing department is specialized in small and medium size series. The operations are realized in cleanrooms in ISO 5 and 7. We propose production with labelling and conditioning of ready to be sterilized medical devices.
We work with big players, as well as with SME's and start-ups.

μ-mim
taisei kogyo co.,ltd.

Taisei Kogyo Co., Ltd.

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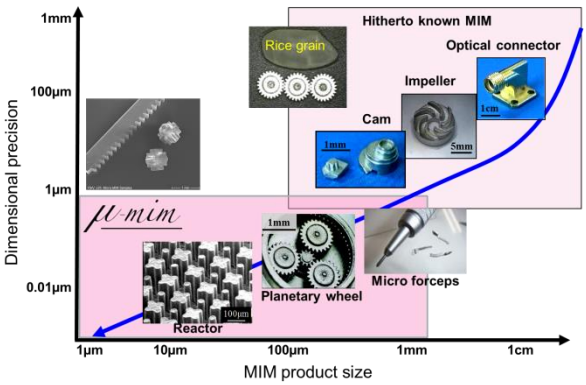

Position in supply chain

Applied Research & Key Experiment	Industrial Research & Development, Prototype	Production, 1st Series	Clinical Tests & Studies	Registration, Approvals & Reimburse-ment	Serial Production
	X	X			X

Activities / products / services

Taisei Kogyo is a Japanese OEM manufacture, which offers state of the art micro-MIM technology to create innovative small metal components for medical and other industries.

Technologies

- Metal Injection Moulding
- Porous metal
- Mould desgin
- SP mould for undercut structure
- Evaluation technique

Markets

- Medical device
- Dental
- Watch & jewelry
- Industrial machine
- Consumer goods

Why use our technology / services?

Please describe in a short text the advantages of your product or technology and in what way users might benefit from applying it, e.g.:

- Wide range of material from SUS, Ti, Cu, Ni, heavy alloy, precious alloy.
- You can create innovative designed metal components that were previously impossible with traditional technology
- The technology is widely used in medical/dental device/machinery, industrial device/machinery, automotive, watch & jewelry, consumer goods, robotics, aeronautics etc.
- One of the top global medical device makers is our customer and they said that they will give us the most difficult projects and easier ones to others!