



eurofins

inpac

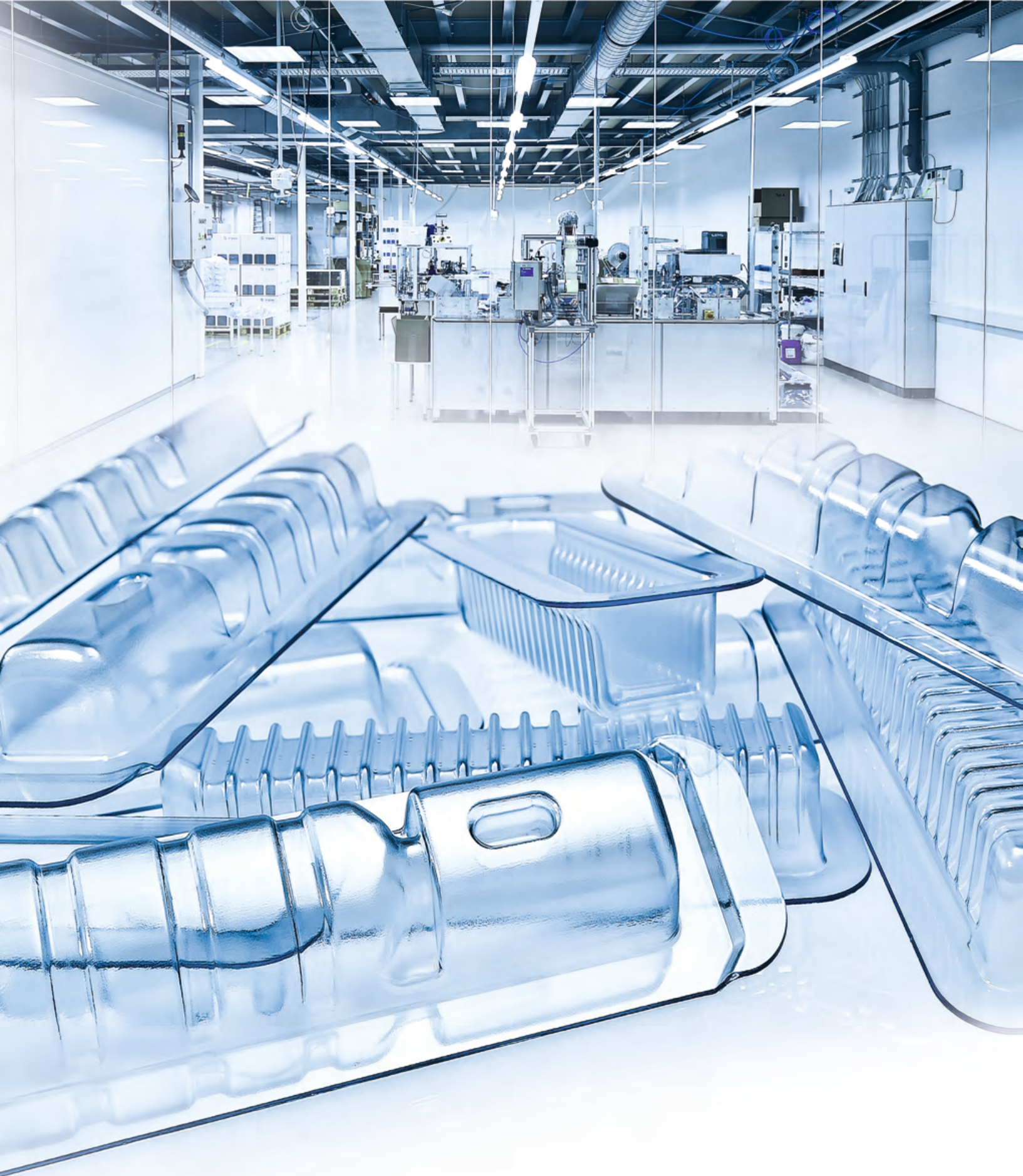


**Safe. Sterile.  
Packaging.**

**Just competent.**

[www.inpac-medizintechnik.de](http://www.inpac-medizintechnik.de)





Contract production and packaging

Packaging design

Production of packaging materials

Cleaning

Assembly

Sterilization

Validation

Documentation

Procurement management

From the product idea up to the medical product ready to sale –  
we ensure best quality at utmost safety.

Certified according to EN ISO 13485 and EN ISO 11135  
Two FDA Registrations – one per site; Japan-Accreditation  
ANVISA-GMP-certificate as Foreign medical device manufacturer.

**100% service from one source.**

That's what Eurofins Inpac Medizintechnik GmbH has proven since its foundation in 2003.



We'll find your solution.  
Customized, fast, economical.

**Just competent.**





## Contract production and packaging

### Packaging design

- 3D construction of blisters and transport insert
- production of prototypes

### Packaging of the products

- with prefabricated blisters and pouches
- with hard/soft blisters and pouches
- in-line production, packaging, and labelling
- qualified state-of-the-art machines and plants with validated processes

### Design of the sales packaging

- folding boxes, shipping cardboards, dispensing boxes, outer packaging, transport packaging

### Procurement of the cardboard

### Procurement of the instructions for use and product inserts

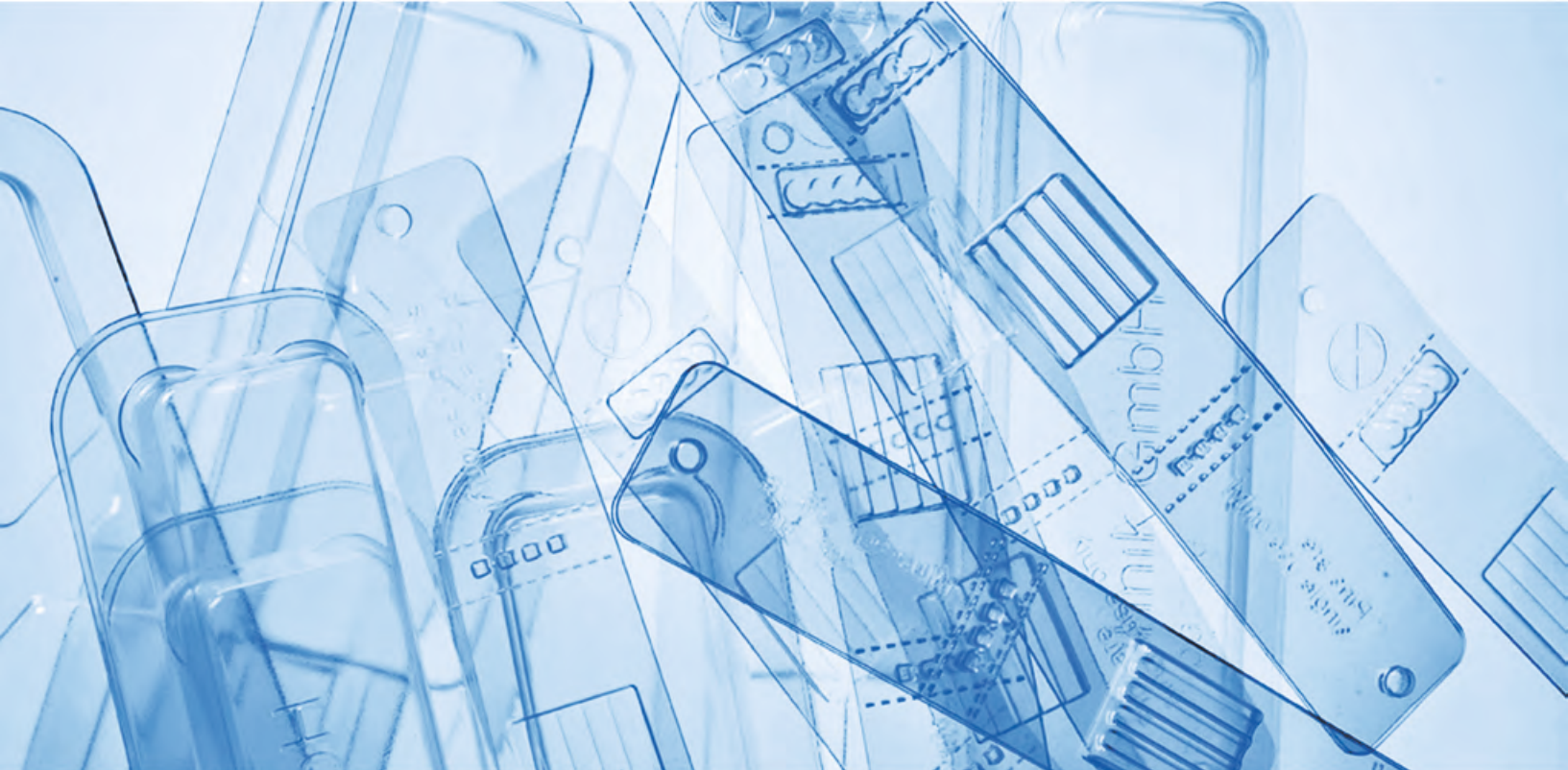
### Cartoning of the products

### Shrinking in foil

### Labeling, identification of the products

- incl. bar codes, patient labels, etc.

### Logistic services



## Packaging design

### Design

We develop individual hard blister packaging solutions for your products. Our engineering department first develops a productspecific blister in the 3D CAD model. The deep drawing tool is then directly generated from this model, thus allowing for extremely fast project throughput.

Aesthetics, functionality and safety are as much at the forefront of our packaging design as are considerations relating to costs, sterilization, safe transportation and the timely and flexible implementation of your requests.

### Label Design

Our labeling department supports you in designing labels, according to ISO 15223-1. We prepare a master label according to your exact specifications, so as to ensure smooth and reliable processing routines.

In this regard, we are able to include UDI requirements, as well as offer you advice regarding the choice of appropriate awarding authorities for unique international item numbers, such as GS1 or HIBC.

In addition to the above, we are able to apply barcodes and DataMatrix codes, as well as customized fonts and company logos.





## Production of packaging materials

### Production of packaging means in clean rooms of ISO class 7

- hard and soft blisters
- peel pouches

### Production of sealing lids

- Tyvek®/aluminum, medical paper for hard blisters in clean rooms of ISO class 7

### Procurement of product components

- e.g. plastic injection parts, titanium turned parts

### Spectroscopic characterization of the packing materials

### Machines and plants with validated processes

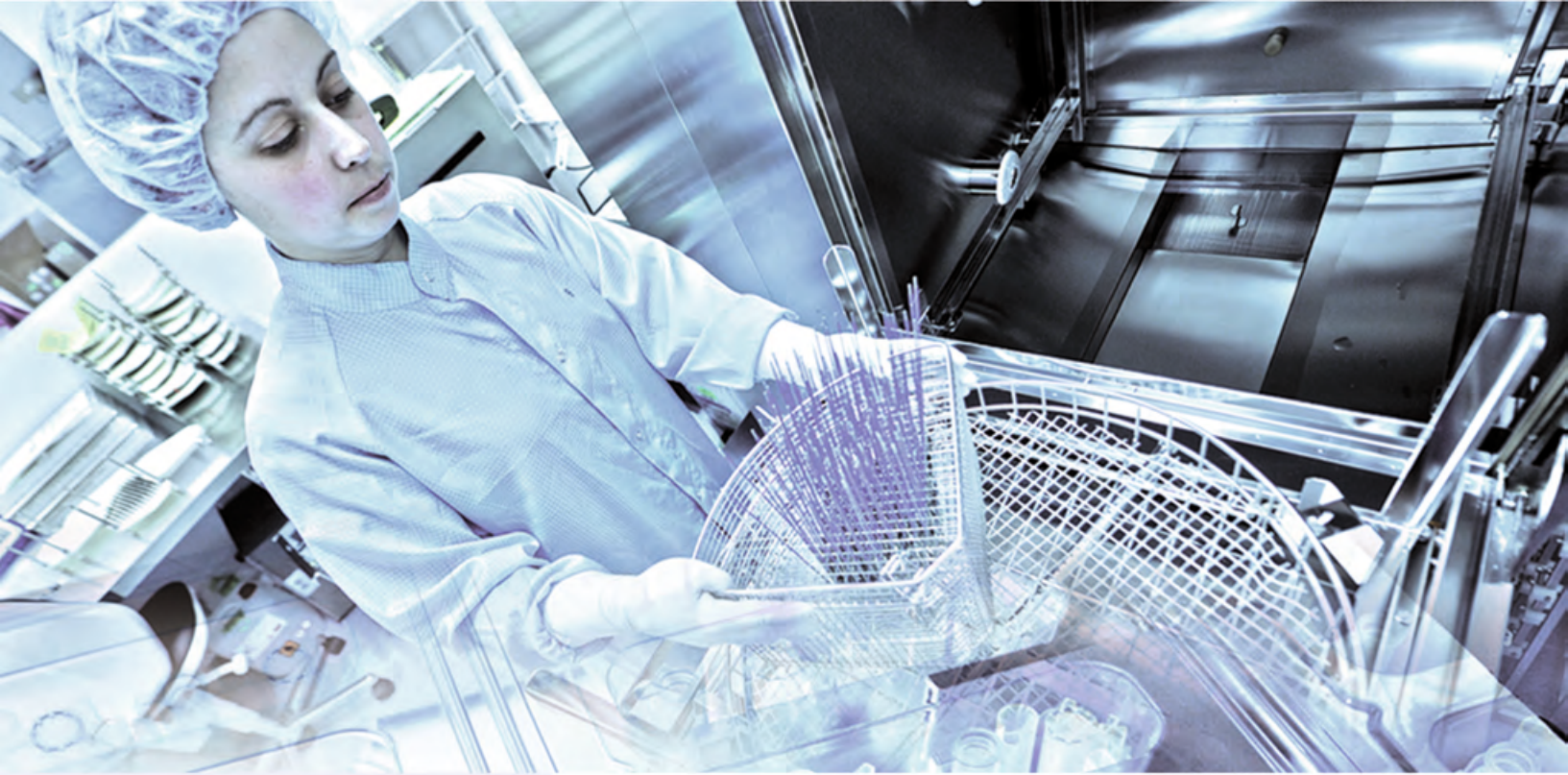
### Form fill seal machines

### Label printing, flexo printing, thermotransfer printing, digital colour printing

Thanks to our in-house production, we can easily produce all conventional packagings for medical products, e.g. hard blisters and soft blisters as well as outer packagings. Any customer requirement that might be defined can therefore be met very flexibly.

International standards are applied in order to ensure the sterility of the products and, thus, the durability of the product until being used.





## Cleaning

Disinfectant cleaning

Ultrasonic cleaning

Cleaning validation

Medical products must be in a defined and constant cleaning condition. The aim is to degrade the bioburden, the particular and the chemical load.

Our experts develop individually adapted cleaning strategies in close collaboration with the customer. We analyze pre-processes with regard to potential contamination. Depending on the product features, cleaning procedures are determined meeting the normative and legal requirements of a medical device.

As we have long-term experience in the areas microbiology, material features, and production processes, we are capable to support our customers to an optimal extent.





## Assembly

**Assembly of the products** according to customer specifications in clean rooms of ISO class 7 (gluing, pressing, coating, ultrasonic welding, functional tests, measuring, control)

**ESD workplace** for the assembly of electronic components

**Procurement of product components**

e.g. thermoformed plastic parts, machined titanium parts

It makes sense to let Eurofins inpac Medizintechnik GmbH produce the medical device, especially in cases where parts of the product must undergo cleaning before being assembled, even if the client has not sufficient clean-room capacity.

Procurement, material planning, and storage of components can also be taken over by us. Our customers benefit from our extensive network of suppliers, as injection molders and metal workers, that are familiar with the medical device laws.

We ensure a hygienically proper sequence and avoid problems at the contact areas as well as unnecessary transports. Our employees are prepared for the production of each individual product in an intensive training.





## Sterilization

### Sterilization with gas and rays

- radiation (gamma)
- gas (ethylene oxide)
- cooperation with certified sterilization companies or in-house by our own EO sterilization plant
- planning and implementation of the validations
- sterilization certificates of the batches
- verification by independent, accredited laboratories

In cooperation with certified sterilization companies, we implement the sterilization of each product in accordance with validated methods and take over the responsibility for the sterility of the products.

The processes are run according to the international standards ISO 11137 (radiosterilization) and ISO 11135 (ethylene oxide sterilization).



## Validation

### Sterilization validations

- according to ISO 11135 (E0)
- according to ISO 11137 Part 1,2,3 (gamma)

### Packaging validation

- DIN EN 868-5, 2, DIN EN 868-5, ASTM F1140, ASTM F88/F88M, ASTM F1929, ASTM F3039
- accelerated aging ASTM F1980
- real-time aging according to an internal standard

### Simulation and testing of transport

- ASTM D4169 DC13  
with preconditioning according to ASTM D4332

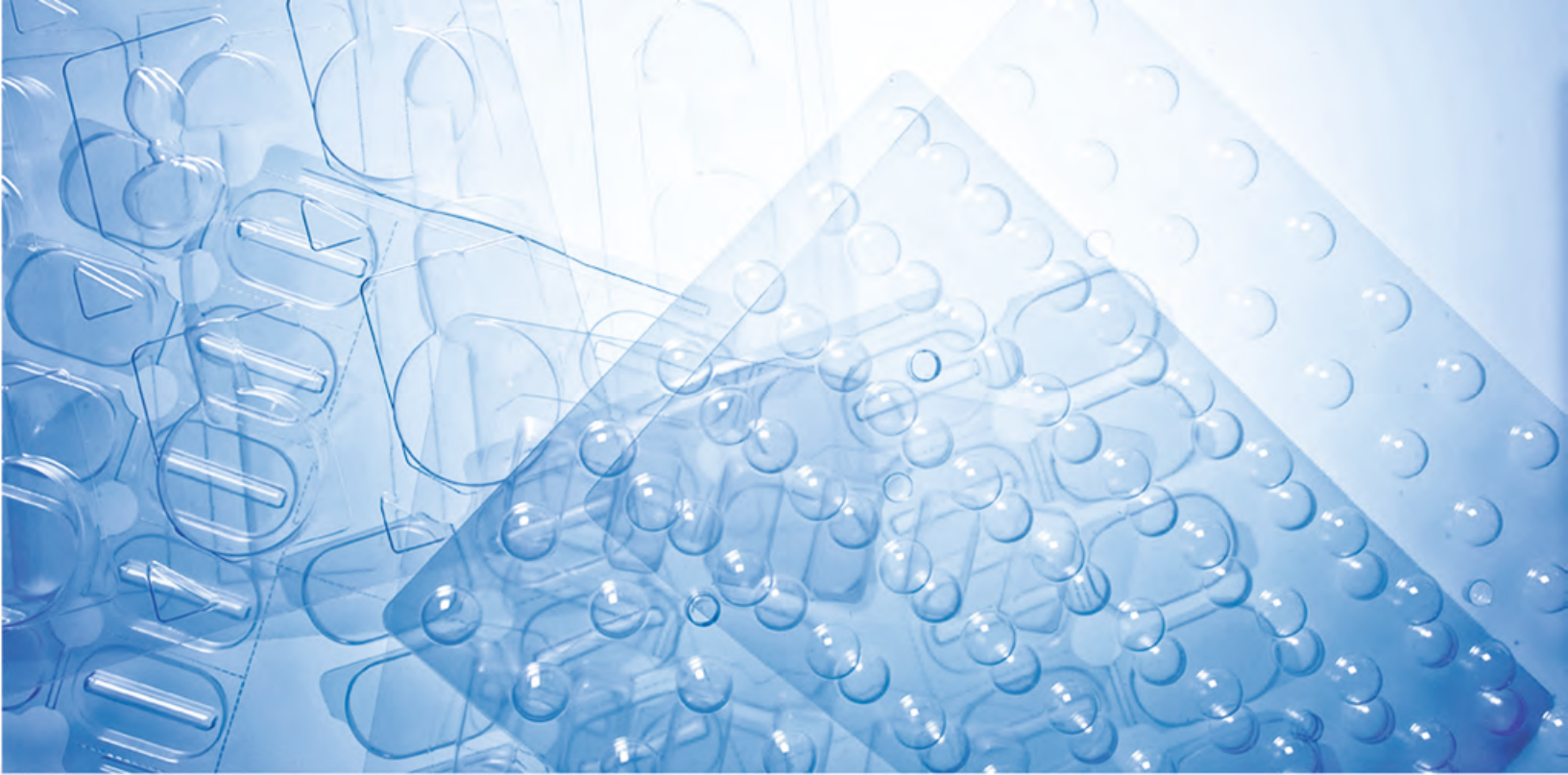
### Packaging tests

- visual inspection, ASTM F1886
- seal strength test, DIN EN 868-5 and /or. ASTM F88/F88M
- dye test, ASTM F1929, ASTM F3039
- burst test, ASTM F1140
- microbiological barrier properties in case of wetness, DIN EN 58953-6
- Bubble Test, ASTM F2096

### Cleaning validations

- examination of germ elimination
- examination of particle elimination
- examination of cytotoxicity
- examination on endotoxins
- further examinations on organic and inorganic residues
- biocompatibility according to ISO 10993-1





## Documentation

Documentation of all process steps

DQ-, IQ-, OQ-, PQ

Product accreditation audit

Suitable machines and plants

FDA registration: Registration Number: 3007515069 (Gewerbestraße),  
3013111980 (Neureutstraße), Owner/Operator Number: 10043226

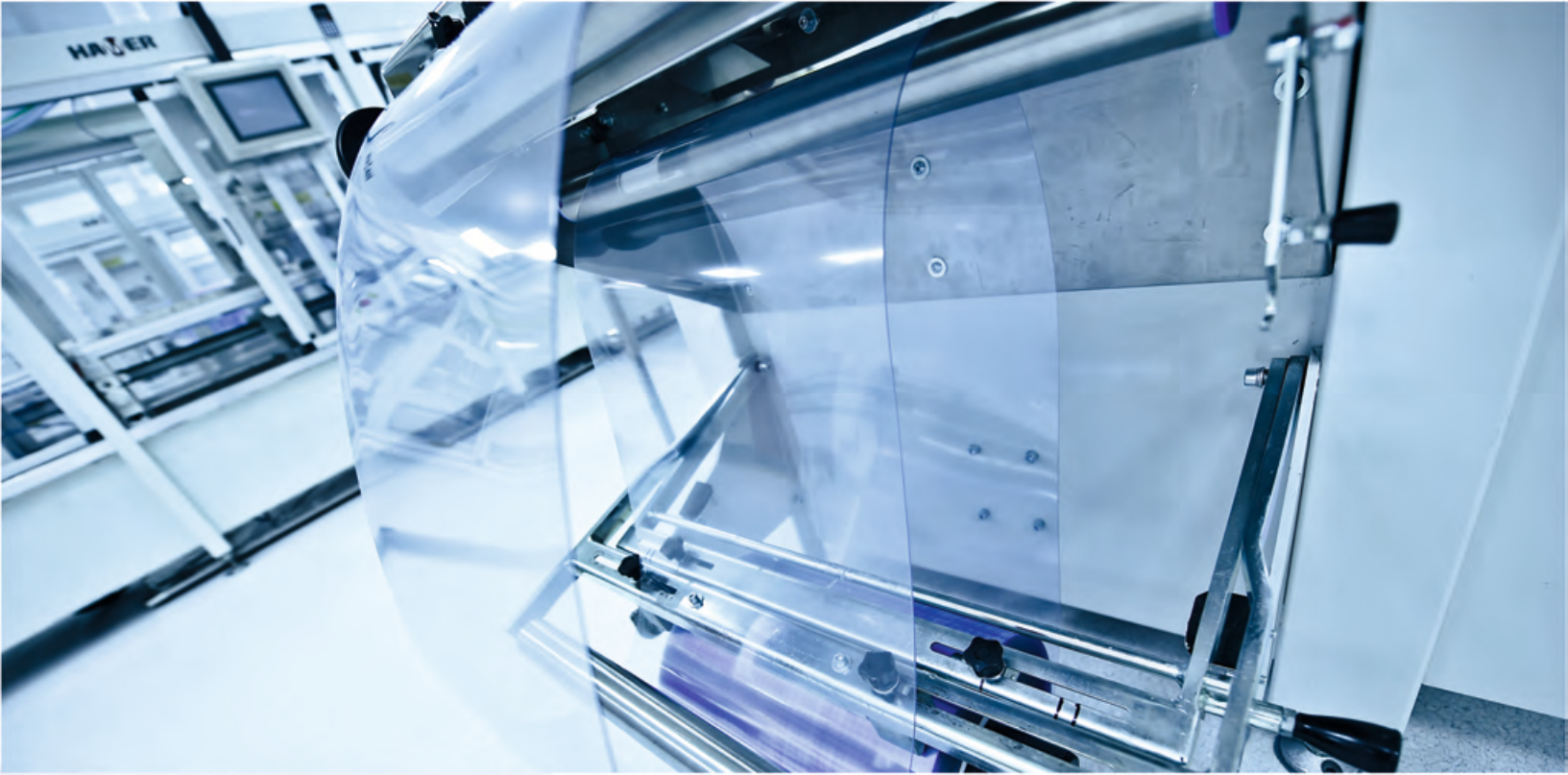
Accredited as foreign medical device manufacturer in Japan

Quality determines our approach throughout all processes. In all work steps, our employees implement our quality management in compliance with EN ISO 9001 and EN ISO 13485.

We record all process steps according to the parameters defined in the validation documents. As basis for the product accreditation, we provide our customers with an extensive documentation and explain this, if desired, in the scope of product accreditation audits.

The documents are generally issued in the English language. Further languages may be provided on demand.





## Procurement management

**We turn your raw products into ready-to-sell medical products.**

Our service also includes the procurement of required packaging components such as

- cardboard packaging
- information leaflet
- user instructions

as well as providing product components such as

- moulded plastic parts
- machined titanium parts
- etc.

In addition, we undertake the processing of medical products, for instance by means of surface treatments such as

- anodic treatment
- etching
- anodising
- kolsterising

**You take care of your core business – we take care of everything else.**





## Our Profile

The Eurofins Inpac Medizintechnik GmbH is a service provider specialising in the cleaning, assembly, packaging and sterilization of medical products.

Our service commitment is something we take to heart, rather than just a task. We strive to successfully place your products on the market, and do everything in our power in this regard. We are forever approachable, friendly, competent and, above all, solution-oriented.

Since our foundation in 2003, we have expanded our production depth to meet our customers' desire for us to become a „One stop shop“.

In this regard, we have developed new packaging approaches with our customers and often carry out the full manufacture of medical products.

New assignments, challenges, as well as customer audits are ways for us to develop further, hand in hand with our customers.

We look forward to working together.



## Company

**Eurofins Inpac Medizintechnik GmbH** was founded in 2003 as a service company for the contract packaging of medical products, and remains today under the management of founding member Dr. Ralph Hermann. Since then, inpac's name has stood for innovative medical technology packaging.

With a growing customer base and developments in other areas, such as pharmaceuticals and biotechnology, vertical integration has been further expanded since 2003, so that product packaging was also extended to include cleaning, assembly, sterilization and full procurement management processes.

Several million medical devices are securely packaged annually at both locations, in the context of our EN ISO 13485 certification. The foundations for this are laid by a team of scientists and engineers who carry out over 350 validations per year in the fields of cleaning, packaging, transport and sterilization.

The company now comprises over 200 employees, based at two locations in Birkenfeld, Baden-Württemberg, with a total production and office space of 5,000 m<sup>2</sup>, which includes approximately 1,700 m<sup>2</sup> for ISO class 7 cleanroom production.

Modern water treatment plants and their own in-house EO sterilization are part of the „One stop shop“ strategy and of our continuous development driven by new technologies.

**Eurofins Inpac Medizintechnik GmbH** is a company that continuously grows with its customers. An additional 7,000 m<sup>2</sup> of expansion space has been actively earmarked at the Birkenfeld site in Neureutstraße for further expansion, in order to also guarantee that we have sufficient capacity and flexibility to keep up with our customers' growth in the future.

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## Contact

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Customized, fast, economical.

**Just competent.**

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