

# Drug Delivery Solutions

**Polymer Syringes**

**Wearable Devices**

**Microneedle Patches**

**Single-Use Biopharma Tubing**

Our purpose.

# We develop solutions for life together with people who care.

RAUMEDIC is your partner for the co-development of polymeric product solutions for drug delivery.

We understand that modern drug delivery systems have to meet demanding requirements, whether for parenteral administration of small molecules or biological agents. We are your competent partner for drug delivery devices from the initial idea to production.

The first step in the development of a device is to understand the application precisely. Whether it's long-life devices with replaceable drug cartridges or disposable products like syringes - we will find the right solution.

**A solution for life.**

## Injection

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Syringe Systems, Wearable Injectors, Auto- & Peninjectors

## Transdermal

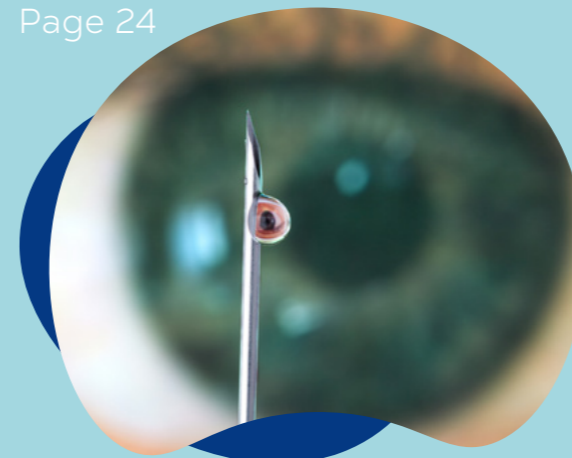
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Microneedle Patches

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Respiratory Tubing, Inhalers

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Single-Use Biopharma Tubing



**»We have a proven track record of bringing combination products to market. Our dedication to polymers in combination with our regulatory experience makes us the ideal partner for drug delivery systems.«**

Lena Wagner,  
Product Manager Drug Delivery

**We go above and beyond the standard.**

# We create Combination Products

Modern pharmaceutical products place high demands on the medical device. The design and handling must ensure maximum patient safety and effective use of the dosages. The selection and testing of the used materials must be taken carefully to ensure no adverse effects occur on the drugs. The specified temperature ranges have expanded considerably, particularly due to the biotechnologically produced substances.

RAUMEDIC has been a manufacturer and marketer of customized medical devices and primary packaging for over two decades. We understand the requirements for the development of medical devices and know exactly how to bring devices efficiently and successfully to approval. With our regulatory services and our comprehensive customer support, your project will be successful.

We accompany our customers from the very first idea and offer a synergy of industry-leading expertise in polymer materials and polymer manufacturing technologies. In addition, we always keep an eye on efficient serial production. Our rapid prototyping with original material and the possibility of small batch production for initial studies make us the ideal partner for the development of innovative drug delivery devices.

**Let's develop the next generation of drug delivery devices!**

The journey of an idea.

# 6 Competences & Capabilities



RAUMEDIC is your partner from the initial idea to serial production of your medical devices. Our expertise in the processing of polymers and silicone is the central pillar and offers an extraordinary synergy of polymeric extrusion, injection molding and further processing steps - **all from one source!**

Through innovative research, we can truly appropriate material selection for best results and rethink medical devices with a focus on sustainability. We focus on human-centered design and develop well thought-out concepts. By early involvement in projects, we can develop quickly and cost-effectively while already taking care of all the requirements of serial production.

Our prototyping methods allow rapid validation and small-scale production for clinical trials. For serial production, we offer comprehensive life-cycle management and quality management.

## Research & Polymer Expertise

70 years of polymeric expertise  
Comprehensive material research and in-house development  
Application-oriented material selection

## Product Idea

Feasibility analysis  
Economic assessment

## Design for Manufacturing

Human centered design  
Initial design und functional concept  
Material and technology selection  
Sustainable materials

## Prototyping

Rapid prototyping with original material  
Small batch production  
3D printing

## Production Concept

Tool design and construction  
Scalable production concept from small series to large volume  
Synergy of extrusion, molding and assembly

## Polymer Manufacturing

DIN EN ISO 14644 Class 7 cleanroom facilities  
GMP compliant production  
Processing all types of thermoplastic polymers and silicones  
Extrusion: co-extrusion, single & multi lumen tubing, microextrusion  
Injection Molding: insert, micro, multi component and overmolding

## Further Processing

Assembly from manual to fully automated  
Printing, punching, bonding, tip- and thermoforming  
Sterilization and individual packaging

## Serial Production

Life-cycle-management  
Change management  
Quality management over full product life cycle

Let's bring your products to market.

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# Regulatory Support



We do not only develop sophisticated medical devices, we also bring them successfully to market. RAUMEDIC offers comprehensive regulatory services and support for the approval of your medical devices.

As a manufacturer and market introducer of our own class III medical devices in the field of neuromonitoring, we know exactly how to create a successful regulatory strategy.

We enable a smooth path from conception to approval of your products. We understand the complex requirements of international medical device directives and ensure that your products meet the required standards.

We work closely with the relevant authorities and help you to launch your products on time and in compliance with the applicable regulations.

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## Quality Management

DIN EN ISO 13485 and 15378 certified  
Quality assurance systems EC Directive 93/42/EEC and 90/385/EEC  
Quality assurance system EU Regulation 2017/745 (MDR)

## Risk Management

DIN EN ISO 14971  
Benefit-risk analysis  
Risk classification

## Technical Documentation

Legally compliant product files  
Construction drawings  
Designation of purpose  
General safety and performance requirements

## Unique Device Identification (UDI)

EUDAMED registration  
Clear identification

## Biocompatibility

70 years of polymeric expertise  
Intense material testing

## Labeling

Provision of all necessary information for leaflet, accompanying materials, labeling, imprints and packaging

## Conformity Assessment

Notified Body Opinion (Art 117)

## Post Market Surveillance

Monitoring product quality throughout its entire lifecycle



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In the world of drug delivery, injection systems are at the center of attention when it comes to the major developments in the global markets. Modern biotechnological vaccines and the growing home care trend are creating great demand for innovative, precise and reliable injection systems.

RAUMEDIC is at the forefront of these innovations and offers customized solutions for pharmacists and medical device manufacturers. More and more patients prefer to undergo their treatments within the familiarity of their homes. Safe and easy-to-use injection systems play a crucial role in meeting these needs.

As a proven partner for pharmacists and device manufacturers in the medtech and pharmaceutical market, RAUMEDIC can support you from an early stage.

**Let's shape the future of drug delivery.**

Tailored to your needs.

# Syringe Systems

The biotechnological production of products and corresponding regulatory guidelines introduce entirely new challenges in the fabrication of primary packaging and medical devices. Therefore, experience and knowledge of materials is all the more important.

RAUMEDIC is the ideal partner for the development and manufacturing of individual syringe systems as well as individual syringe components. We are just as familiar with the regulatory requirements as we are with the needs of the medical staff and patients. We find the right solution for each individual challenge.

In the development and production of custom assemblies and disposable products, we offer you highest freedom of design to realize the best possible combination of drug and device. We are happy to support you even before the clinical phases begin.

**Benefit from our extensive expertise in the world of medical polymers!**

## What you can expect

- High freedom of design and customized individual components
- Special concepts for biologics, small molecules, vaccines and cell therapy
- Polymer solutions for chemical integrity, drug integrity and transparency (COC, COP)
- Experience in the production of primary packaging (DIN EN ISO 15378) and combination products
- Improved injection results through optimized handling and minimal dead volume



**1 Plunger Rods & Backstops**  
Precisely fitting, ergonomic components for syringe handling and accurate drug administration.

**2 Syringe Stoppers**  
Tailor-made, injection molded stoppers for optimum breakaway forces, dynamic friction and minimal dead volumes.

**3 Labeling**  
Exact scaling, e.g. by pad, inkjet or laser printing for precise medication dispensing and avoidance of dosing errors.

**4 Needle Integration**  
Secure and strong connection by bonding or overmolding. Fully automatic processing of the needles.

**Temperature Resistance**  
Material resistance down to -80°C enables safe handling of sensitive biologics and pharmaceuticals.

**Ready to fill**  
Packaging and sterilization compatible for aseptic filling (e.g. tub/nest, trays).

Upgrade your syringe system.

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# Silicone Syringe Stoppers

Good handling is an essential quality criterion for syringe systems. Simple and precise handling can ensure the exact dosing of drugs – and therefore safe drug administration.

The syringe and plunger stoppers have a significant influence on the overall performance of injection systems. Compared to conventional rubber stoppers, RAUMEDIC's glide-optimized silicone stoppers are characterized by lower friction with the syringe body. This reduces the breakaway forces of the system and requires less effort from medical personnel. As a result, the use of silicone oil can be significantly reduced or even completely avoided.

Particle-free production by injection molding offers maximum freedom of design in terms of shape and requires no further washing processes.

## What you can expect

- **Low gliding friction and breakaway forces**
- **Complete elimination of silicone oil possible**
- **Low number of extractable components**
- **Deep freezable: temperature and dimensional stability down to -80°C**
- **Suitable for all common sterilization methods**



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Mobility for the patient.

# Wearable Devices

Drug delivery is undergoing a transformation, and wearable injectors are at the heart of this trend. Wearable devices enable precise, convenient and monitored drug delivery. Nevertheless, their development is quite challenging.

RAUMEDIC is an experienced partner in the industry and has extensive know-how. Our expertise ranges from material science to regulatory processes. We are ready to shape the future of efficient and patient-friendly drug delivery together with you.

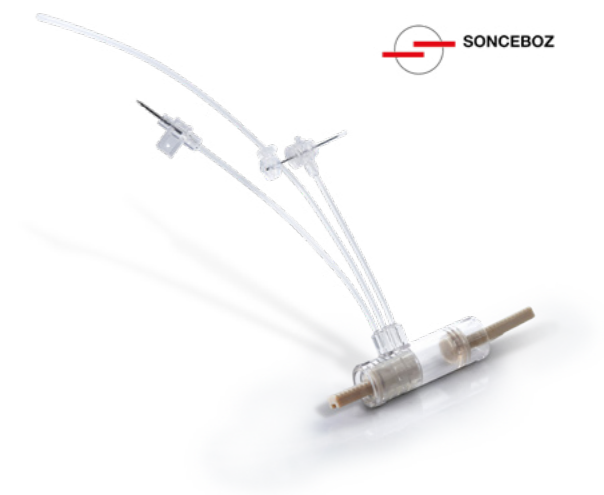
## What you can expect

- Experience in the development of wearable devices
- System solutions from a single source: disposable unit, stopper, reservoir, fluid path and tube set
- Regulatory experience in the approval of combination products
- High quality manufacturing for absolute leak tightness
- Coextruded tubing perfectly matched to the active ingredient and external influence
- Know-how in miniaturization of components and tubing



## Fluid Path

- High-precision microtechnology manufacturing
- Needle integration by overmolding or bonding
- Completely sealed connection of the assembly
- Coextruded tubing: robust outer layer and inert inner layer
- Full control of flow rate
- Completely sterile and packaged subassemblies on request



## Device Body & Disposable Unit

- Customized system solutions
- Complete unit from a single source
- Glide-optimized reservoir stoppers
- Customized medication reservoir
- Integration of visual feedback

## Soft Cannula

- Device-specific development
- Designed to remain in patients' bodies for several days
- Tightest tolerances by micro injection molding or extrusion
- Precise assembly
- Increase of wearing comfort
- Reduction of pain perception



## Tubing Sets for Off-body Devices

- Multilayer coextruded tubing sets
- Inert inner layer and flexible outer layer
- Kink resistant, robust and durable
- Designed to remain in patients' bodies for several days



»We offer a unique synergy of extrusion, injection molding and assembly that makes development very effective and always keeps feasibility and applicability in mind.«

Daniel Mielert,  
Head of Product Management  
Injection Dosing Devices



**Scan me!**  
Scan this QR-Code with the camera of your smartphone and experience augmented reality with our RAUMEDIC products. No App needed!



**Making self injection a safe injection.**

# Pen- and Autoinjectors

For years, the healthcare sector has been following a clear trend toward patient care in the home environment. Well-designed and, above all, user-friendly devices are essential for safe self-medication. Pen and auto-injectors offer an intuitive and safe solution in many therapeutic areas.

Successful platform solutions require innovative designs and state-of-the-art manufacturing technologies. Combining reusable platforms with disposable components offers a sustainable approach.

With decades of experience in medical technology, RAUMEDIC is the ideal development partner for complex and reliable mechanisms in the smallest dimensions.

**Let's develop the next generation of drug delivery systems!**

## What you can expect

- **Reliable needle safety systems**
- **Compact designs and miniaturized mechanisms**
- **User-friendly solutions**
- **Sustainable devices e.g. made of biopolymers**
- **High volume and high precision manufacturing**
- **Customized assembly, labeling & packaging**





Ready to revolutionize drug delivery.

# Microneedle Patches

Microneedle patches are innovative and precisely manufactured medical devices for the transdermal administration of drugs and vaccines. Tiny needles safely and effectively deliver active ingredients through the outer layer of the skin.

**This form of administration offers decisive advantages:**

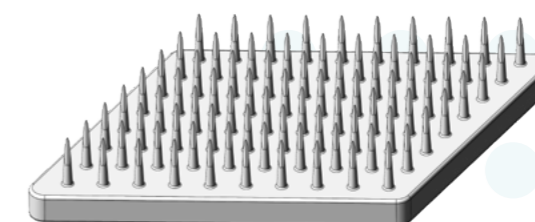
- + **Painless application and minimal invasiveness**
- + **Increased drug efficacy through targeted local application**
- + **Precise dosage and high bioavailability of the drug**

RAUMEDIC's many years of experience in micro injection molding make us the ideal development partner and manufacturer of tools and packaging systems for transdermal drug delivery. We offer comprehensive materials expertise for the highest compatibility between the active ingredient and the device.

**Let's shape the future of drug delivery together and improve patients' quality of life.**

What you can expect

- **Highest design freedom in terms of geometry and dimension**
- **High precision injection molding and assembly in clean room environment**
- **Micro injection molding technology with shot weights as low as to 0.004g**
- **Concept development, prototyping and "ready-to-fill" serial production**
- **Regulatory support**





**Full control und supreme purity.**

# Intravitreal Syringes

The eyes are the window to the world. Drug treatment of the eyes requires highly precise and reliable injection systems that are easy to handle. Through easy handling and high-quality materials matched to the drug, we strive to make treatment as pleasant and uncomplicated as possible for both the patient and the medical staff.

One major challenge in the area of ophthalmic injection systems is the reduction of silicone oil without negatively affecting the fundamental handling of the system. RAUMEDIC offers the perfect solution with specially developed syringe stoppers, which even allow the complete elimination of silicone oil.

As an experienced medical technology manufacturer, RAUMEDIC covers all areas of the development and production of drug delivery systems. This includes the selection of suitable materials, the design of syringes with optimized handling, as well as high-precision manufacturing, assembly and packaging in clean room environments.

**Our goal is to make all forms of therapy as pleasant and safe as possible.**

What you can expect

- **Silicone oil-free syringe systems**
- **Maximum emptying of the syringe system**
- **Low levels of particulate matter**
- **Safe and precise dosing thanks to optimized syringe handling**





**Accurate and easy dosing.**

# Oral Dosing Devices

For medications to exert their optimal effect, the correct dosage is crucial. Oral drug delivery is one of the most commonly used methods of drug therapy because it is simple, precise and cost-effective.

The unique challenges in oral drug delivery include stability, bioavailability and release of drug products in the gastrointestinal tract, patient adherence and acceptance, and medical device safety and hygiene.

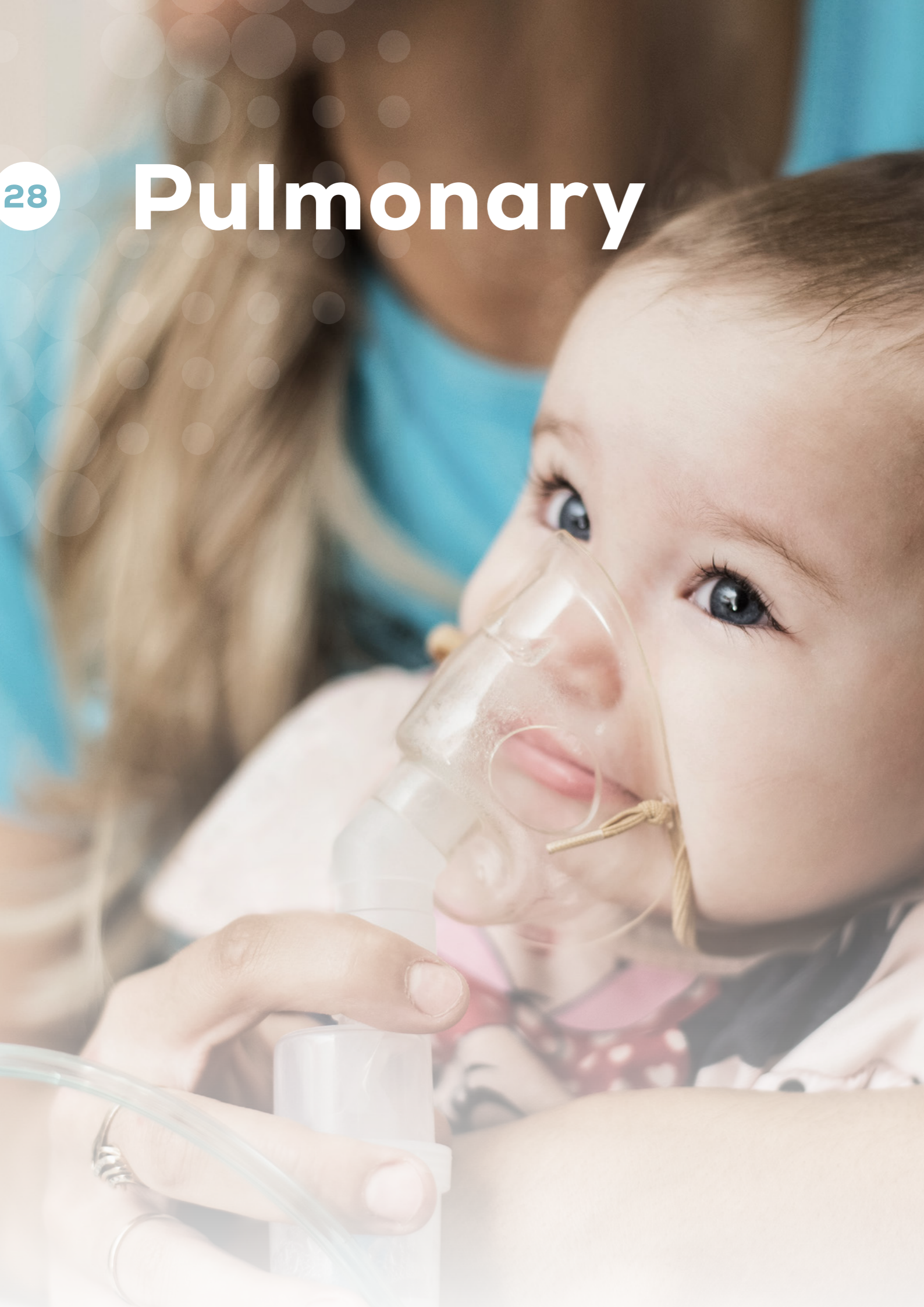
To meet these challenges, you need an experienced and innovative partner who can provide customized solutions for reliable medical devices. RAUMEDIC is your partner in this area.

We support you in the development of innovative solutions that ensure flexible and precise drug delivery - all according to your individual requirements.

## What you can expect

- **Individual dosing systems for the administration of liquids, granules and powders**
- **Precise drug dosing due to latching function**
- **Integration of haptic, visual and acoustic feedback during dosing**
- **Safe application due to fixable dosing volume**
- **Design freedom in terms of shape, color, etc.**
- **Individual packaging, e.g. in flowpacks or blisters**





Ensuring unmatched durability.

## Respiratory Tubing & Inhalers

Inhalation applications play a crucial role in drug delivery and are used in the therapy of various respiratory diseases such as asthma, COPD, cystic fibrosis or allergies. Here, active ingredients are inhaled directly into the lungs as a gas, vapor or aerosol, where they can act quickly and in a targeted manner. The advantages of this method include high bioavailability, low systemic exposure and good tolerability.

Effective and safe inhalation therapy requires high-quality medical devices that ensure optimal particle size, accurate dosing and user-friendly application.

We offer a wide range of processing technologies for medical polymers, combined with expertise in medical device and disposable product design. We support you in the selection of suitable materials, design and prototyping, manufacturing according to certified standards and product registration. Our products are successfully used in nebulizers and inhalers by well-known companies in the industry.

**We look forward to successfully implementing your project as well.**

What you can expect

- **Connection of tube to connector by overmolding - without usage of adhesives**
- **Integration of seals and valves thanks to our silicone expertise**
- **High quality products for demanding daily use**
- **Reduced condensate formation**
- **Highly flexible and durable tube sets**



# 30 Pharma Fluid Processing

- Platinum Silicone Tubing (SIL)
- Thermoplastic Tubing (TPE)
- Braided Tubing (SIL)
- PVC Tubing
- FEP Tubing
- Connectors



Scan me!

Discover our comprehensive  
Biopharma Fluid Handling Portfolio!

Meeting pharma fluid processing needs.

# 31 Single-Use Biopharma Tubing

Fluid handling is a crucial area in pharmaceutical production that places high demands on the quality, safety and reliability of the systems used. Tubing systems are an essential part of many applications that transport or dispense fluids.

RAUMEDIC offers you a comprehensive portfolio of tubing and accessories for use in the pharmaceutical and biopharmaceutical industry. Our tubing systems are specifically designed to meet the demanding requirements of fluid management.

**Choose from a wide selection of high-quality tubing and benefit from our short delivery times!**

What you can expect

- **Buying from the source**
- **Product supply and fast delivery times**
- **Quality assurance**
- **Customer specific dimensions on request**





Creating sustainable value.

# Sustainability at RAUMEDIC

Sustainability is a crucial factor in the world of drug delivery devices. Modern devices are essential for many therapies and improve the health and well-being of millions of people around the world. At the same time, however, they generate a significant amount of waste and consume energy and resources. Therefore, it is of great importance to design and manufacture drug delivery devices that are safe, effective, and environmentally friendly.

The global sustainable drug delivery market is expected to grow rapidly in the coming years. This growth will be driven by factors such as the rising prevalence of chronic diseases, the aging population, the increasing use of pharmaceutical self administration and home health devices, and advances in technology and innovation.

RAUMEDIC is well positioned to address sustainability challenges and opportunities in drug delivery devices. We have implemented several measures to reduce our environmental footprint. These include researching and using bio-based and biodegradable polymers, carefully separating waste, and using energy-efficient processes and technologies.

## What you can expect

- **Customer workshops on sustainability**
- **Materials research on biopolymer alternatives**
- **Optimization of carbon footprint through transportation, energy management and materials**
- **Close cooperation with packaging manufacturers**

## Certifications and awards

- **Certified energy management system according to DIN EN ISO 50001**
- **Certified environmental management system according to DIN EN ISO 14001**
- **International sustainability and carbon certification ISCC PLUS**
- **EcoVadis sustainability recognition level silver**



Scan me!

Discover our recent RAUMEDIC sustainability report.





What can we do for you?

# Global Service

We are here for you - worldwide. RAUMEDIC has a global network and we are happy to assist you with any questions regarding our products and services. Whether you need an individual consultation or a technical support, we are only a phone call or an email away.

**Let's connect!**



**Experience**  
More than 70 years in the field of medical technology



**Workforce**  
Approx. 1,300 employees worldwide

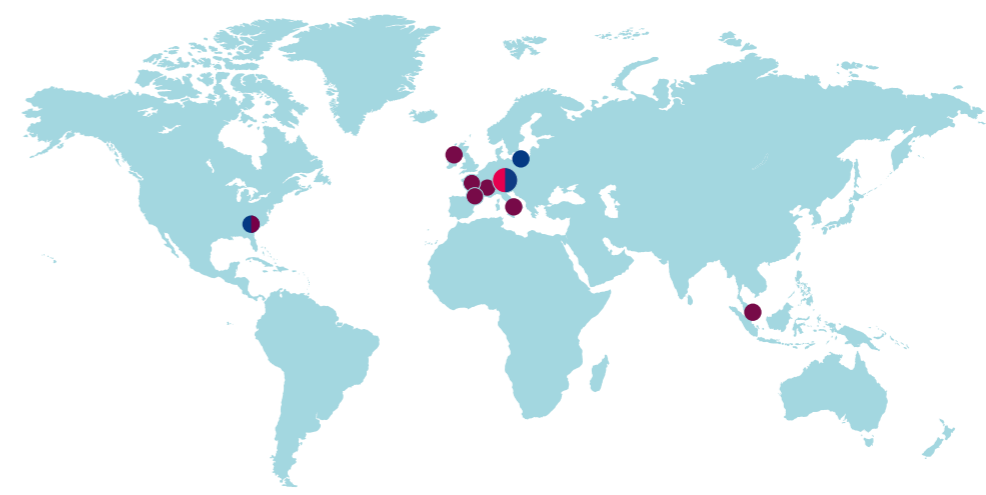


**REHAU Group**  
Guarantor for long-term partnerships



**Cleanroom production (Class 7)**  
Germany: ~9,000 m<sup>2</sup> (~96,875 sq. ft.)  
Estonia: 350 m<sup>2</sup> (3,767 sq. ft.)  
USA: 1,115 m<sup>2</sup> (12,002 sq. ft.)

Locations | RAUMEDIC Group



- **Headquarters:** RAUMEDIC AG, Helmbrechts, DE
- **Production Facilities:**  
Germany: Helmbrechts, Zwönitz, Feuchtwangen; US: Mills River; EE: Tallinn
- **Sales Offices:**  
Germany, USA, Austria, Italy, Northern Ireland, Singapore, France, Switzerland

Our extensive worldwide sales network means that customers and interested parties can be personally assisted and advised on site:

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