raumedic

Biopharma Fluid Handling

Standard & Custom Single-Use Solutions for Fluid Processing

raumedic.com

We serve Biopharma.

RAUMEDIC – Your Partner for Pharma Fluid Handling

The biopharmaceutical industry deserves a partner who understands its unique challenges. At RAUMEDIC, we combine more than 70 years of manufacturing excellence with deep expertise in fluid processing to deliver solutions that are safe, reliable, and tailored to your needs.

To support you in every step of your value chain, we go beyond supplying components. We work with you to develop customized single-use tubing sets, transfer systems, and innovative product solutions that meet the highest standards of quality and compliance. From concept to completion, RAUMEDIC is by your side.

What Sets Us Apart

Direct from the Source
In-house material development, extrusion, and injection molding at five production sites across three countries.

Integrated Solutions
From premium tubing and connectors to fully assembled single-use systems – all from a single source.

Uncompromising Quality
Biocompatibility, chemical resistance, sterilizability, and regulatory compliance are at the core of everything we do.

Flexibility and Customization
Whether standard products or tailor-made designs, we bridge the gap between standardization and individualization.

More information about RAUMEDIC
raumedic.com/downloads/factsheet

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Our Capabilities for Your Success

Extrusion

Purity and Cleanliness

RAUMEDIC extrudes single-use tubing in standard or custom dimensions, manufactured under strict clean-room conditions. Our materials are engineered for minimal extractables and leachables, ensuring purity and safeguarding against contamination.

Molding

High-Quality Components Made In-House

Our injection molding expertise enables the production of precision components, such as connectors and specialty parts, tailored to your application. Whether self-manufactured or sourced, every component meets stringent regulatory requirements.

Assembly

Ready-to-Use Single-Use Systems

RAUMEDIC combines tubing and molded components into fully assembled single-use systems, including tubing sets for critical processes. We deliver ready-to-use solutions that reduce complexity in your operations.

From Product Idea to Serial Production

The path from the initial idea to the finished product can be long and demanding. RAUMEDIC acts as a reliable problem solver and strives to make this path as smooth as possible for its customers. We realize product concepts according to individual customer requirements and are personally committed to achieving real results that exceed our customers' expectations.






1 Product Idea

- **Customer's Product Idea**
  Starting point of the project
- **Idea Evaluation and Consultation**
  Assessing optimization and feasibility
- **Goal Definition**
  Jointly setting project objectives

2 Material Development

- **Material Development**
  Selection of suitable materials
- **Material Testing**
  Biocompatibility, compliance, and other criteria
- **Optimization**
  Adjusting materials for the next production phases, if necessary

3 Product Concept

- **Preliminary Design & Feasibility Study**
  Initial drafts and reality check
- **Requirements Analysis**
  Considering technical requirements and customer needs
- **Development of a Preliminary Manufacturing Concept**
  Based on the product life cycle

4 Design & Prototyping

- **Design for Manufacturing**
  Detailed development of a production-ready design
- **Physical Prototypes**
  Tangible sample parts for final feasibility confirmation
- **Production Layout**
  Integrating all insights for manufacturing

5 Manufacturing

- **Manufacturing Technologies**
  Extrusion, injection molding, assembly
- **Pilot Production**
  Small batches for validation
- **Serial Production**
  Scalable manufacturing solutions

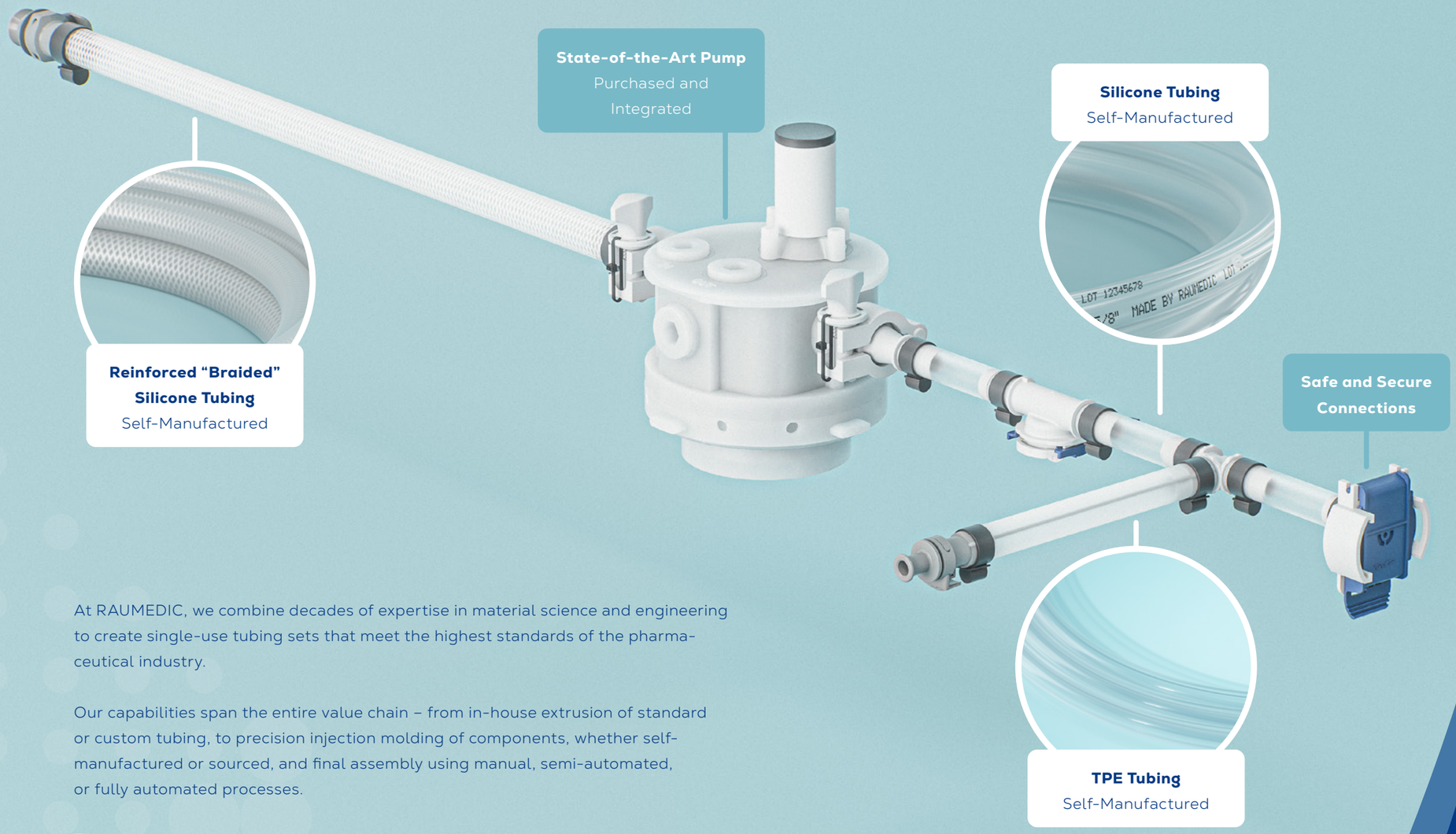
6 Services

- **Sterilization**
  Compliance with cleanliness requirements
- **Regulatory Services**
  Certifications and labeling
- **Technical Documentation**
  Complete and comprehensive documentation

Phases 2–4 are cyclical learning processes where design and development status are iteratively adjusted to achieve the highest product quality and performance. RAUMEDIC utilizes each new learning opportunity to optimize manufacturing layout and scalability of mass production. Technical specifications and regulatory requirements are not only met but exceeded whenever possible to ensure optimal performance of the medical or pharmaceutical end-use application.

Standard Components,

Custom Solutions!



At RAUMEDIC, we combine decades of expertise in material science and engineering to create single-use tubing sets that meet the highest standards of the pharmaceutical industry.

Our capabilities span the entire value chain – from in-house extrusion of standard or custom tubing, to precision injection molding of components, whether self-manufactured or sourced, and final assembly using manual, semi-automated, or fully automated processes.

The result: ready-to-use systems that are as individual as your application – designed for safety, reliability, and efficiency.

Beyond Products: Services That Make the Difference

Tailor-Made Packaging Solutions

Custom packaging concepts designed for transport safety and compatibility with gamma sterilization.

Support with IQ, OQ, and PQ

Expert assistance throughout installation, operational, and performance qualification.

Extensive Validation Documentation

Validated standard materials and products with dedicated Validation Guides for smooth qualification and compliance.

Design, Manufacture, and Packaging of Single-Use Tube Sets for Crossflow Filtration in a TFF Machine

One Partner. Full Value Chain.

Under tight timelines, a leading system manufacturer tasked RAUMEDIC with delivering six single-use tube set variants for a tangential flow filtration (TFF) platform – built to tight tolerances and specific BOMs.

Starting from existing drawings, our team identified design and interface optimizations and aligned specifications jointly with the customer.

Read the full case study on our website
raumedic.com/insights/single-use-tubings-crucial-role-as-cross-flow-filtration-equipment

Manufacturing and Assembly

Each set integrated up to 28 components and ~9 meters of tubing. We combined SILMOTION® (platinum-cured silicone), BRAIDMOTION® (reinforced silicone), and THERMMOTION® (TPE) with a balanced mix of self-manufactured and qualified purchased parts. Controlled assembly delivered ready-to-use systems tailored to process needs.

Agility and Quality – Built In

A cross-functional squad brought the right expertise to every work package, enabling rapid responses to change requests without compromising compliance. When purchased parts fell short, RAUMEDIC swiftly qualified an alternative supplier, keeping the project on schedule – proof of our lived quality culture: “Reliably Safe”.

Packaging and Qualification Support

The customer further commissioned custom packaging engineered for transport safety and sterilization compatibility, leveraging the efficiency of a one-stop shop. RAUMEDIC supported the qualification process to accelerate time-to-operation.

Result

An integrated, compliant suite of single-use tube sets – delivered under pressure, optimized for performance, and backed by RAUMEDIC’s robust supply network.

Tubing and Connectors for Pharma Fluid Handling

At RAUMEDIC, we deliver more than components – we provide complete solutions for pharmaceutical and biopharmaceutical fluid handling. Our portfolio combines premium tubing and precision connectors, designed to meet the highest standards of safety, compliance, and performance. Whether you need standard dimensions or fully customized designs, RAUMEDIC ensures reliability from material development to final assembly.

Our standard tubing range includes Silicone, TPE, PVC, and high-performance fluoropolymers like FEP – each engineered for specific process requirements. Complementing this, our Polycarbonate Connectors ensure secure, aseptic connections for single-use systems.

Together, they form the perfect match for your critical applications.

SILMOTION®

Highly Resistant Platinum-Cured Silicone Tubing

- Two variants: SILMOTION®-T/H featuring Shore A Hardness of 60 or 80, depending on process requirements
- High biocompatibility: ISO 10993-4, -5 and USP 88 class VI tested
- Fulfills requirements of European Pharmacopoeia 3.1.9. and regulation 21 CFR, § 177.2600
- No animal derived materials (BSE/TSE risk-free)
- Tested extractable profile
- Manufactured in ISO 14644-1 Class 7
- From -60°C (-76°F) to +200°C (+392°F): No loss of integrity or deterioration
- Sterilization possible with gas, steam, gamma or X-rays
- Patented & only available from RAUMEDIC:
  Low-Tack Surface for Silicone Tubing which provides a less sticky surface
- Enhanced pumping lifetime under the rigorous use of a peristaltic roller pump with SILMOTION®-T
- Shorter processing times due to consistent and reliable flow rates

More information and sizes overview at
raumedic.com/silmotion

TPE Single-Use Tubing

THERMMOTION®

Highly Resistant, Weldable, and Sealable Tubing for Pharmaceutical Fluid Handling

- High biocompatibility: ISO 10993-4, -5, and USP 88 class VI tested
- European and American standards: ISO 3826-1, USP 661 compliant
- No animal derived materials (BSE/TSE risk-free)
- BPOG tested Extractable Profile
- Manufactured in ISO 14644-1 Class 7
- From -55°C (-67°F) to +135°C (275°F): No loss of integrity or deterioration
- Sterilization possible with gas, steam, gamma or X-rays
- Extended pumping lifespan when used with peristaltic roller pumps
- Enhanced flow rates
- Optimized for cell growth (free of tDtBPP, CAS 31750-04-04)

More information and sizes overview at
raumedic.com/thermmotion

BRAIDMOTION®

High-Pressure Resistant Fluid Handling Tubing

- High biocompatibility:
  ISO 10993-4, -5, USP 85, USP 87, USP 88 class VI tested
- No animal derived materials (BSE/TSE risk-free)
- Fulfills requirements of the European Pharmacopoeia 3.1.9 and USP 661
- Fulfills requirements of FDA regulation 21CFR, §177.2600 and §177.2800
- BPOG-tested Extractable Profile: Validated for non-braided silicone tubes, applicable for fluid contact material
- Manufactured in ISO 14644-1 Class 7
- From -20°C (-4°F) to +135°C (+275°F): No loss of integrity or deterioration
- Sterilization possible with gas, steam, gamma or X-rays
- Patented & only available from RAUMEDIC:
  Low-Tack Surface for Silicone Tubing which provides a less sticky surface
- Pressure tested & approved: Tested in accordance with ISO 1402
  at ambient conditions for non-sterile and sterilized tubing

More information and sizes overview at
raumedic.com/braidmotion

PVC Tubing

Polyvinyl Chloride

Our PVC tubing is durable, chemically resistant, and biocompatible. It ensures safe and reliable transfer of sensitive media. With excellent flexibility, transparency for visual control, and compliance with global standards, our PVC tubing is ideal for a wide range of single-use applications.

- **Biocompatible**
  Meets USP Class VI and ISO 10993 standards
- **Chemical Resistance**
  Withstands acids, bases, salts, and solvents
- **Flexible & Transparent**
  Easy handling and visual flow control
- **Sterilizable**
  Compatible with steam, gamma, and EtO sterilization

More information and sizes overview at
raumedic.com/application-areas/pharma-fluid-handling/pvc-tubing

FEP Tubing

Fluorinated Ethylene Propylene

RAUMEDIC FEP tubing is the premium choice for pharmaceutical fluid processing where chemical resistance, purity, and compliance are critical. Its exceptional durability and transparency make it ideal for demanding single-use applications, ensuring safe and reliable performance under various processing conditions.

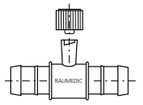
- **Outstanding Chemical Resistance**
  Suitable for a wide range of aggressive media
- **Biocompatible & Sterilizable**
  Safe for contact with biological fluids
- **Transparent & Durable**
  Easy visual inspection and robust under stress
- **Regulatory Compliance**
  Meets stringent pharma industry standards

Connectors

RAUMEDIC's precision-molded polycarbonate connectors ensure secure, contamination-free couplings while meeting the highest regulatory standards. Designed for versatility and aseptic integrity, they are the perfect match for our premium tubing solutions.

Tubing Connectors with Luer Lock

Tube Connector



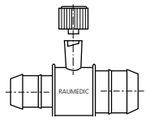
Dimension [inch]
3/16" x 3/16"
1/4" x 1/4"
3/8" x 3/8"

Tubing Connectors without Luer Lock

Tube Connector

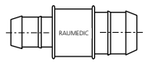
Dimension [inch]
3/16" x 3/16"
1/4" x 1/4"
3/8" x 3/8"

Reduction Connector



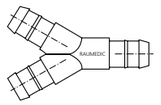
Dimension [inch]
3/16" x 1/4"

Reduction Connector



Dimension [inch]
3/16" x 1/4"
1/4" x 3/8"

Y Connector



Dimension [inch]
1/4" x 1/4" x 1/4"
3/8" x 3/8" x 3/8"

Sustainable Solutions

At RAUMEDIC, sustainability is built into our materials strategy and operations: we help customers reduce upstream Scope-3 footprints by integrating ISCC PLUS mass-balance materials and advancing biopolymer development – without compromising product performance or compliance. Our approach combines sustainable raw materials with on-site renewable energy initiatives to create measurable, scalable impact for pharma and medtech supply chains.

Learn more
raumedic.com/insights/commitment-to-sustainability

"For us, sustainable action is not a trend – it's a fundamental conviction and a key driver of future innovation. Together with our customers, we act to conserve resources, protect the environment, and take social responsibility for future generations."

Maximilian Hofmann, Sustainability Manager

Efforts to Optimize Our Footprint

At our headquarters, a new biomass energy center and roughly 2,500 solar panels are designed to supply renewable heat and power, targeting up to 85% less CO_2 emissions from heating and strengthening energy resilience. These measures complement our material strategy to deliver lower-footprint products and a more sustainable supply chain for our customers.

ISCC PLUS

Through the ISCC PLUS mass-balance approach, we replace fossil feedstock with bio-attributed or circular alternatives while keeping products chemically identical – enabling a seamless, low-risk switch for selected lines (e.g., TPE tubing) and speeding up qualification. Building on ISCC PLUS certifications at key RAUMEDIC sites (incl. Helmbrechts HQ and the Feuchtwangen plant), we help reduce product carbon footprints without changing form, fit, or function.

Certificate Holder ISCC International Sustainability & Carbon Certification

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Quality Requirements

Manufacturing takes place in a controlled environment in a clean room certified in accordance with DIN EN ISO 14644-1, Class 7 and Grade C in accordance with the EC GMP Directive.

RAUMEDIC also employs a quality management system based on DIN EN ISO 13485 and can guarantee consistently high product quality as a result.

In addition, RAUMEDIC is certified in accordance with the primary packaging standard ISO 15378. ISO 15378 includes a number of supplemental requirements that apply in particular to primary packaging that comes in direct contact with pharmaceuticals.

All processes and materials used by RAUMEDIC are validated and qualified article-specifically within the framework of development, so that our customers, with regard to product registration in accordance with MDR (Medical Device Regulation EU 2017/745) using RAUMEDIC articles, can access corresponding information and documents within the framework of the joint contractual agreements. A detailed agreement on the scope of qualification and validation with the customer is required.

REGISTERED FDA REGISTERED

PRIMARY PACKAGING ISO 15378 MATERIALS

CLEANROOM ISO 14644 CLASS 7

SUSTAINABLE ENERGY ISO 50001 MANAGEMENT

ENVIRONMENTAL ISO 14001 MANAGEMENT SYSTEM

RAUMEDIC MDR ready SINCE 2020

QUALITY MANAGEMENT ISO 13485 SYSTEM

RAUMEDIC cGMP STANDARDS

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