

**Extrusion**  
Moulding  
Assembly

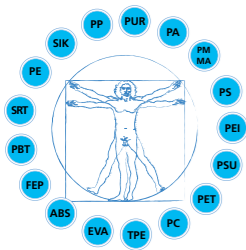


**RAUMEDIC®**  
— Lifeline to Health —

## Pharma Fluid Handling

The tubing range  
for fluid handling in  
bio-pharmaceutical  
processes





## The right material for the right application

RAUMEDIC is manufacturing polymeric components and sub-assemblies for the medical and pharmaceutical industry for over 60 years. The product range covers tubing and moulded parts as well as complete assemblies that are used for a diverse range of therapies and applications.

In the production of infusion lines, catheters, implantable materials and pharmaceutical filling lines, RAUMEDIC has built-up wide-ranging and comprehensive expertise on the interactions of flow media with polymers and the qualification of suitable polymer formulations according to current norms and regulations.

We are developing novel packaging concepts with the pharmaceutical industry and we supply tubing and other fluid handling products for pharmaceutical production. We are happy to provide you with extensive and qualified advice on the selection of suitable materials for your specific application. We await your challenge!

### Safety is our first priority!

- QM-System certified to ISO 13485
- ISO 9001
- Clean room production according to ISO 14644, ISO Class 7 (= 10000)
- GMP standards
- CE-certification

### The tubing range for fluid handling in bio-pharmaceutical processes

- FluiSil®
- FluiSet®
- Customer-Specific Projects

# FluiSil®

Silicone tubing for biopharmaceutical applications



Braided Silicone Tubing

FluiSil is our established tubing range for bio-pharmaceutical applications.

With comprehensive test certification and a material of extraordinary chemical inertness, FluiSil is the material of choice for fluid handling in bio-pharmaceutical processes.

## Options

- Silicone, addition cross-linked with organic-platinum catalysts
  - Silicone, peroxide cross-linked on Methyl-Vinyl-Polysiloxane basis
  - If necessary, reinforced by braiding for high-pressure applications
  - Printing
  - Coils wrapped in double PE-bags
  - „Low-Tack“: Significantly reduced surface friction
- Benefits:
- Reduced stickiness
  - Much reduced dust particle adhesion
  - Permanent printing / marking (InkJet)
  - Easier handling in assembly and packaging

## Features & Benefits

- Very good tear strength in peristaltic pumps
- Resistant against weak acids and bases
- Extraordinary heat and cold resistance
- Water repellent
- Very stable molecular bonds
- Free of antioxidants, plasticisers or accelerators
- Detailed validation documentation available

## Tests / Approvals

- E.P. 3.1.9
- USP Class VI Implant test, systemic toxicity tests and intracutaneous tests
- Cytotoxicity acc. to ISO 10993-5
- Haemolysis test acc. to ISO 10993-4
- Pyrogen free, LAL-Test acc. to USP
- FDA 21 CFR 177.2600
- BfR, sections A XV, B II XV
- USP (381)

## Applications

- Peristaltic pumps
- Pharmaceutical filling lines
- Disposable sets
- Insulin
- Hormones
- Plasma, blood components
- Vaccines, Serums



FluiSil-tubing in different dimensions

**SIK8649**

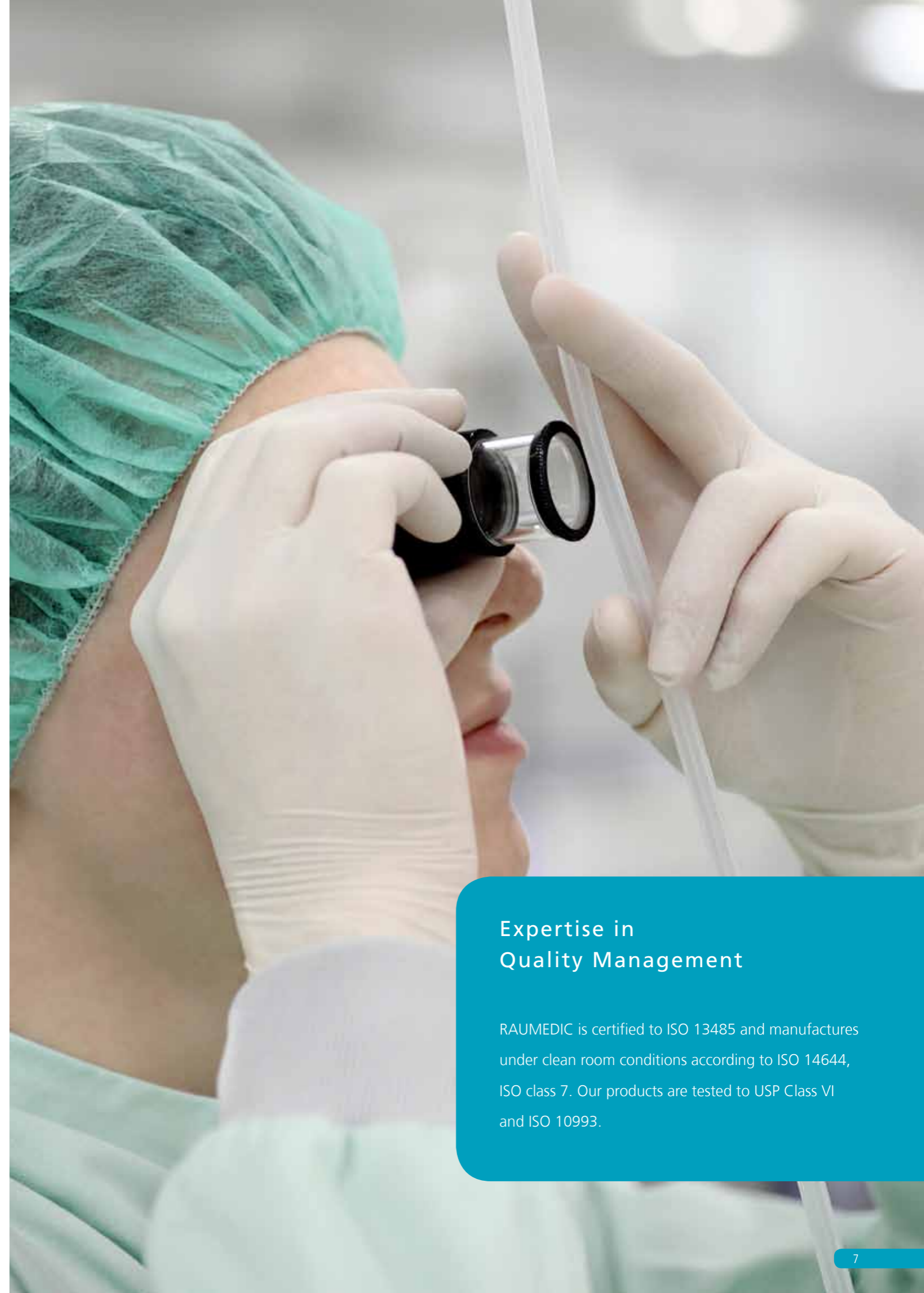
- Transparent
- Platinum cross-linked silicone, suitable for pumps
- Shore-hardness DIN EN ISO 868: A 60 +/- 5
- Temperature range: -60°C to +200°C
- Tear strength (MPa) DIN EN ISO 527: min. 8.0
- Elongation at break (%) DIN EN ISO 527: min. 500%
- Tear propagation strength (N/mm) ASTM-D 624 B: min. 35
- Pharma conformity (FDA, Master File Number MAF 1341; European Pharmacopeia 3.1.9, USP-class VI)
- Batch linked test certificate
- Printing with physiologically inert printing ink
- Suitable for sterilisation with Gamma irradiation to 32 kGy, Steam to 134°C, ETO
- Tubing coils packed in double PE-bags



FluiSil-tubing in double PE-bag

**SIK8363**

- Transparent
- Peroxide cross-linked silicone
- Shore-hardness DIN EN ISO 868: A 60 +/- 5
- Temperature range: -60°C to +200°C
- Tear strength (MPa) DIN EN ISO 527: min. 7.0
- Elongation at break (%) DIN EN ISO 527: min. 300-600%
- Tear propagation strength (N/mm) ASTM-D 624 B: min. 20
- Pharma conformity (FDA; European Pharmacopeia 3.1.9, USP-class VI)
- Batch linked test certificate
- Printing with physiologically inert printing ink
- Suitable for sterilisation with Gamma irradiation to 32 kGy, Steam to 134°C, ETO
- Tubing coils packed in double PE-bags



**Expertise in Quality Management**

RAUMEDIC is certified to ISO 13485 and manufactures under clean room conditions according to ISO 14644, ISO class 7. Our products are tested to USP Class VI and ISO 10993.

# FluiSet®

Tubing sets for  
bio-pharmaceutical  
applications

**FluiSet** are completely assembled, sterile packed tubing sets for fast tubing connections in bio-pharmaceutical manufacturing and filling processes.

The sets consist of our established FluiSil-tubing and filling funnels matched to tri-clamp connectors.

## Options

- **FluiSil**-tubing (addition- or peroxide cross-linked)
- Funnels for DIN 32676 tri-clamp
- Set with or without enclosed washers
- Braided silicone tubing
- Customer specific versions are possible, even non-DIN variants
- Sterile packaging
- LSR-moulded parts as tubing connectors

## Features & Benefits

- Biologically inert
- Excellent toxicological properties
- Gamma-sterilised
- Detailed validation documentation available

## Areas of application

- Fluid handling in bio-pharmaceutical processes
- Blood components, plasma derivatives
- Serum production
- Liquid filling lines

## Tests / Approvals

### Tubing:

- E.P. 3.1.9
- USP Class VI Implant test, Systemic toxicity test and Intracutaneous test
- Cytotoxicity test acc. to ISO 10993-5
- Haemolysis test acc. to ISO 10993-4
- Pyrogen free, LAL-Test acc to USP
- FDA 21 CFR 177.2600
- BfR, sections A XV, B II XV
- USP (381)

### Funnel:

- Cytotoxicity acc. to ISO 10993-5
- Haemolysis test acc. to ISO 10993-4
- Pyrogen free, LAL-Test acc. to USP



Funnels and washers

**Funnels**

- Material: PP natural

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- European Pharmacopeia 3.2.2

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- USP Class VI

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- FDA, Master-File-Number MAF 9040

**Washers**

- Acc. to DIN 32676

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- Material: Platinum-Silicone (FDA)

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- Colour: translucent

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- Suitable for pharma- and food-applications as recommended by BfR "XV.Silicone" and FDA §177.2600.



FluiSet in sterile packaging

**RAUMEDIC  
Project Management**

Your specific ideas are converted into finished products by our team lead by the project manager.

Our application technicians, process engineers, quality managers and sales staff ensure that your project is time, cost and risk managed to ensure reliable production.

## Customer-Specific Solutions

Individual Components for Biopharmaceutical Use

Innovative solutions custom made to your requirements

Beside our standard fluid management products FluiSil and FluiSet we offer customised assemblies and components. We are your development partner in the areas of polymer filling needles, sampling port systems for R&D purposes, fluid transfer systems, single-use sets and many more.



Filling Needles

### Plastic Needles for Pharmaceutical Filling

- Customer-specific material and needle holder
- Leak-free connection of a complete tubing system possible
- Gamma-sterilisable
- Fabricated by RAUMEDIC



Examples of Sampling Systems

### Sampling Systems

- Individually tailored to customer requirements
- Use of weldable tubing for sterile sampling



Components for a bridging system in silicone tubing

### Silicone Bridging System

- Reinforced silicone tubing (ID up to 25.4 mm)
- LSR / LIM moulded tri-clamp
- Metallic compression sleeve
- Pressure resistant
- Autoclavable



Connectors in thermoplastic materials

### Connectors

- Y-connectors, 3-way distributors, reduction connectors
- Material: polyamide, free of bisphenol A
- Leak-free connection with **FluiSil**-tubing
- Various sizes as requested
- Other materials as requested

## The RAUMEDIC Services

- Extrusion of silicone tubing inc. reinforcing
- Customer-specific production (ID: from 0.1 mm to 30 mm)
- Extensive pump tests & tests on extractables/leachables
- Injection moulding of tri-clamps and plastic connectors
- Stainless steel components available on request
- Assembly, testing concept and packaging according to customer requirements
- Sterilisation and sterilisation validation
- Material documentation and specification inc. production of RAUMEDIC drawings
- On-site support / flexible order processing
- Single source for: **extrusion, injection moulding & assembly**



# Service worldwide! Let RAUMEDIC be your development partner!

Thanks to our global sales network we can service and advise  
our worldwide customers individually and locally.



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