

Technical and regulatory requirements on Pharma silicone tubing

Michael Drechsel
Senior Product Engineer
Raumedic AG

RAUMEDIC at a glance



Team worldwide
> 1.300



Experience
> 70 Years



REHAU
= Family



Innovation
≈ 15 % R&D



Sales
≈ 200 Mio. €

Our production sites

In the US, Germany and Estonia

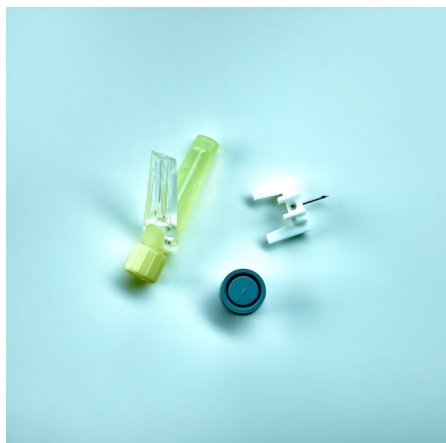


Raumedic Product Portfolio

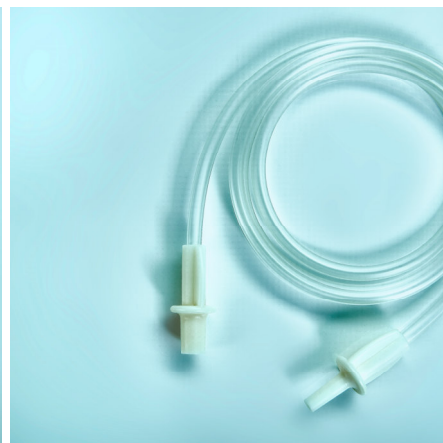
A one-stop shop for the medical and pharmaceutical industry



Tubing



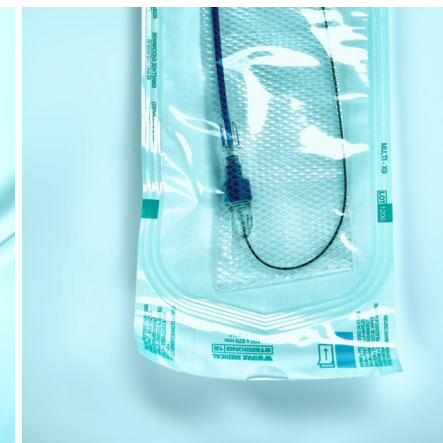
Molded Parts



Semi-finished products



Complex systems



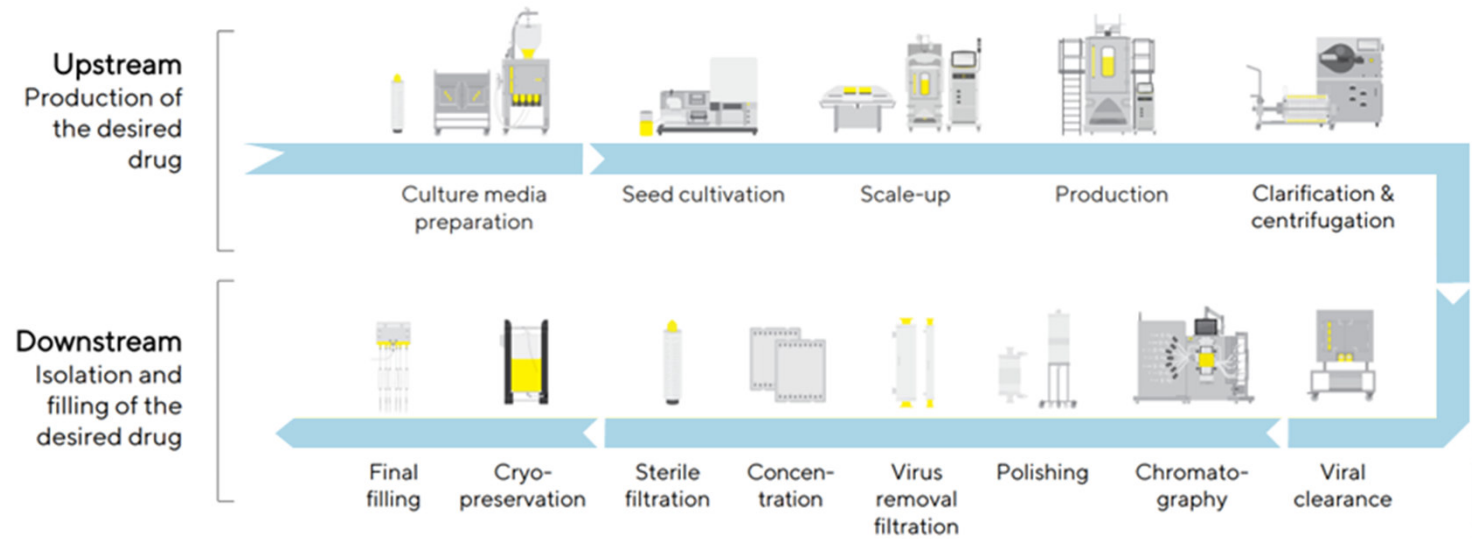
Finished Products

Bio-Pharmaceutical Production Process



Production environment
ISO 7 clean rooms.

Production of active
pharmaceutical
ingredients (APIs) by
living cells.



Main application areas of silicone tubing



Transfer



Pump



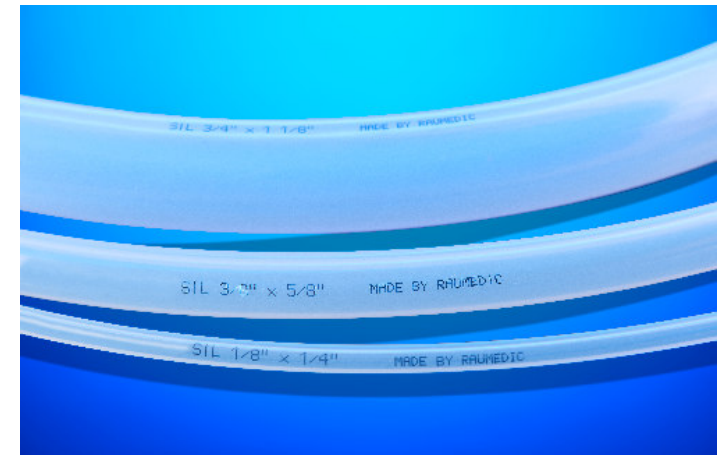
Ports

Why is silicone the material of choice?

Pros	Cons
✓ Free of plasticizers/ stabilizers → Minimized Extractables/Leachables	✓ Not weldable/ sealable
✓ Excellent biocompatibility	✓ Limited modification of properties
✓ Non-creeping, ideal retention behavior	✓ High gas permeability
✓ Excellent pumping behavior and life-time	✓ Chemical compatibility
✓ Constant properties over a wide temperature range	
✓ All sterilization methods applicable	
✓ Inertness	
✓ High gas permeability	

Technical requirements

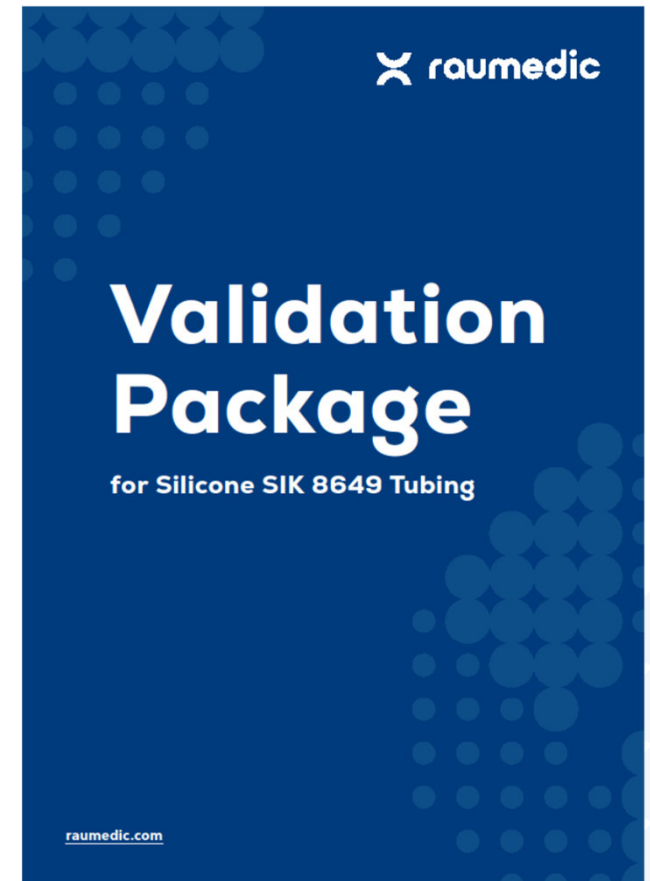
- Platinum-cured materials between 50 – 80 Shore A
- Operating pressure up to 6 bar
- Pump performance
 - Repeatability
 - Precision
 - Lifetime
- Handling performance (e.g. flexibility, surface stickiness)
- Cleanliness
 - Production environment
 - (Raw) Material
 - Particle generation (spallation)



Regulatory requirements

Products have to be pre-validated in terms of technical and functional specifications:

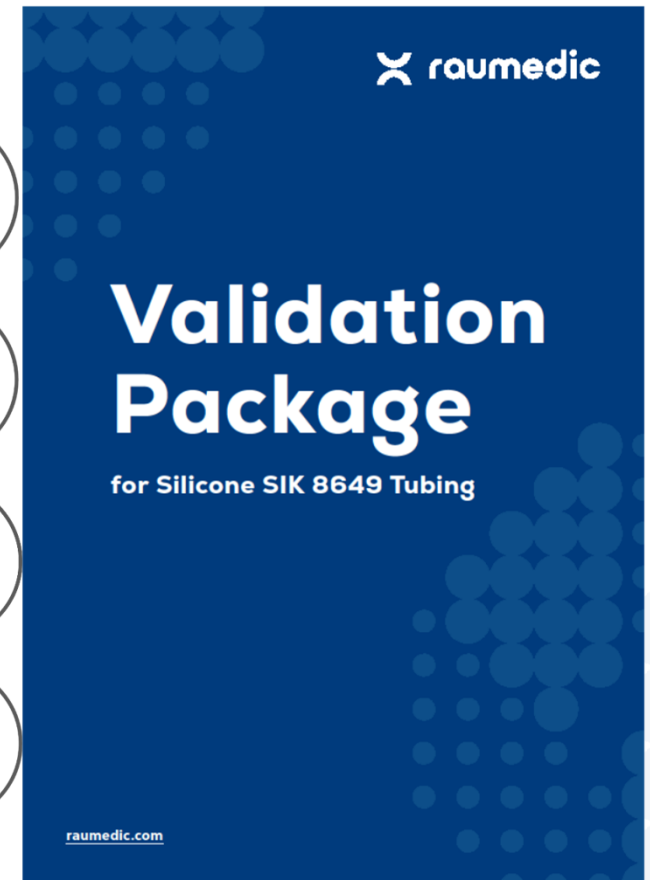
- Physico-chemical properties (e.g. E.P. 3.1.9)
- Biocompatibility (e.g. USPs <88>, <87>, <85>)
- Extractables profile (e.g. USP <665>, BPOG)
- Functional test data (e.g. pressure testing, pumping life time and flow rates)



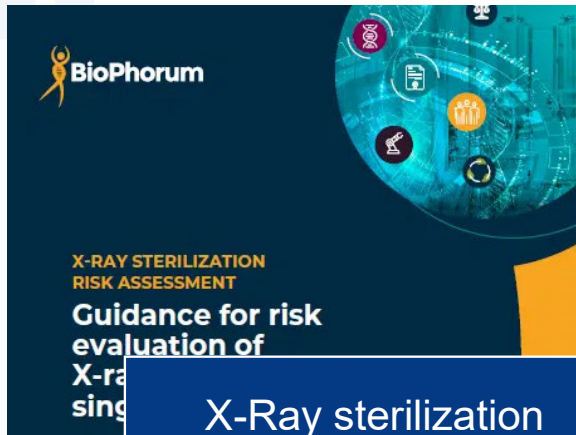
Regulatory requirements

A robust quality system is essential

- Certifications (e.g. ISO 13485, ISO 14644)
- Extended customer service (e.g. Audits of 3rd party notified bodies)
- Traceability
- Security of supply
- Monitoring system (e.g. USP <788>, clean room monitoring, bioburden)



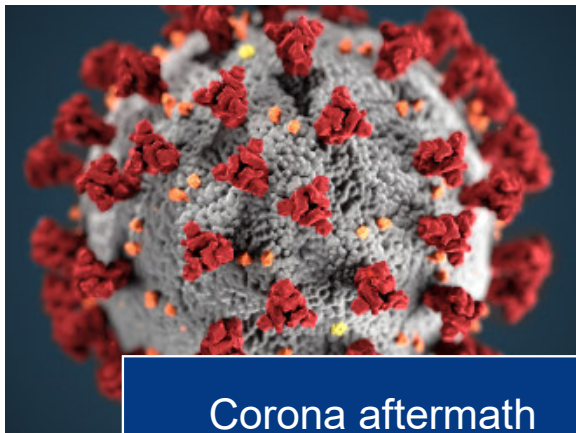
Outlook/ Hot topics



X-Ray sterilization



Single-Use-Systems (SUS)



Corona aftermath



Sustainability, Recycling, CO²-Footprint

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