



Product Service

# Certificate

No. Q5 053268 0081 Rev. 03

**Holder of Certificate:** **RAUMEDIC AG**  
Hermann-Staudinger-Strasse 2  
95233 Helmbrechts  
GERMANY

**Certification Mark:**



**Scope of Certificate:** **Design, development, production and sales of**  
**- systems, components and semi-finished products**  
**made from polymer materials for medical devices and**  
**medical accessories, based on extrusion, injection**  
**moulding and assembly techniques**  
**- precision measurement catheters with accessories**  
**- dosing systems with accessories**  
**- compounds for the manufacturing of products for**  
**medical applications**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 053268 0081 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5_053268_0081_Rev.03)

**Report No.:** 713347151

**Valid from:** 2025-04-01

**Valid until:** 2028-03-31

**Date,** 2025-01-22

Christoph Dicks  
Head of Certification/Notified Body



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**Applied Standard(s):** ISO 13485:2016  
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)  
Medical devices - Quality management systems -  
Requirements for regulatory purposes

**Facility(ies):** **RAUMEDIC AG**  
Hermann-Staudinger-Strasse 2, 95233 Helmbrechts, GERMANY

Design, development, production and sales of  
- systems, components and semi-finished products made from  
polymer materials for medical devices and medical accessories,  
based on extrusion, injection moulding and assembly techniques  
- precision measurement catheters with accessories  
- dosing systems with accessories

**RAUMEDIC AG**  
Hermann-Staudinger-Strasse 6, 95233 Helmbrechts, GERMANY

Production and sales of  
- systems, components and semifinished products made from  
polymer materials for medical devices  
and medical accessories, based on extrusion and assembly  
techniques

**RAUMEDIC AG**  
Crailsheimer Strasse 34, 91555 Feuchtwangen, GERMANY

Production and sales of  
- components and semi-finished products made from polymer  
materials for medical devices and medical accessories, based on  
extrusion  
- compounds for the manufacturing of products for medical  
applications

**RAUMEDIC AG**  
Am Mühlgraben 10, 08297 Zwönitz, GERMANY

Design, development, production and sales of  
- systems, components and semi-finished products made from  
polymer materials for medical devices and medical accessories,  
based on assembly techniques  
- precision measurement catheters with accessories

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