



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 053268 0081 Rev. 04

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. 04](http://www.tuvsud.com/ps-cert?q=cert:Q5_053268_0081_Rev_04)

Report No.: 713375637

Valid from: 2025-06-20

Valid until: 2028-03-31

Date, 2025-06-20

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

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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
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

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