



Deutsche  
Akkreditierungsstelle  
D-ZM-11321-01-00



Product Service

# Certificate

No. Q5 016329 0031 Rev. 02

Holder of Certificate:



**sfm medical devices GmbH**

Brückenstraße 5  
63607 Wächtersbach  
GERMANY

Certification Mark:



Scope of Certificate:

**Design and development, production and distribution as well as contract manufacturing of sterile, non-active single use medical devices and related components in the field of puncture cannulas, transfer devices and needles for pharmaceutical preparation and drug delivery and biopsy devices.  
Ethylen oxide sterilization services.**

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\\_016329\\_0031\\_Rev\\_02](http://www.tuvsud.com/ps-cert?q=cert:Q5_016329_0031_Rev_02)

Report No.:

713342892

Valid from:

2025-05-06

Valid until:

2028-05-05

Date, 2025-05-06

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):** **sfm medical devices GmbH**  
Brückenstraße 5, 63607 Wächtersbach, GERMANY  
  
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contract manufacturing of sterile, non-active single use medical  
devices and related components in the field of puncture cannulas,  
transfer devices and needles for pharmaceutical preparation and  
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**safemed medical devices s.r.o**  
Trabantská 292, 19015 Praha 9, CZECH REPUBLIC

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