



Product Service

# Certificate

No. Q6 126376 0001 Rev. 01

**Holder of Certificate:** **Otto Rüttgers GmbH & Co. KG**  
Roonstr. 17-19  
42699 Solingen  
GERMANY

**Certification Mark:**



**Scope of Certificate:** **Manufacture & distribution of sterile scalpel blades and non-sterile scalpel handles for detachable blades. Provision of manufacturing services for sterile scalpel blades and non-sterile scalpel handles for detachable blades**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), 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:Q6 126376 0001 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q6 126376 0001 Rev. 01)

**Report No.:** 713368886

**Valid from:** 2025-08-05

**Valid until:** 2028-08-04

**Date,** 2025-07-09

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):** **Otto Rüttgers GmbH & Co. KG**  
Roonstr. 17-19, 42699 Solingen, GERMANY

Manufacture of sterile scalpel blades

**Otto Rüttgers GmbH & Co. KG**  
Schmalzgraben 7, 42655 Solingen, GERMANY

Manufacture of semi-finished non-sterile scalpel blades for sterile scalpel blades and non-sterile scalpel handles for scalpel blades.  
Final Inspection of sterile scalpel blades and non-sterile scalpel handles for scalpel blades.  
Distribution, Provision and Storage of sterile scalpel blades and non-sterile scalpel handles for scalpel blades.

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