

EU Certificate

for the assessment of the
quality management system



according to Medical Device Regulation (EU) 2017/745 Annex IX Chapter I+III

As a Notified Body of the European Union DEKRA Certification GmbH certifies, that the
manufacturer

Richard Wolf GmbH

Single Registration Number (SRN): DE-MF-000007048

Pforzheimer Str. 32, 75438 Knittlingen, Germany

applies a quality management system according to Annex IX Chapter I+III of the Medical Device Regulation (EU) 2017/745 for the medical devices listed in the annex. This certificate is based on the assessments listed in CNo50593-00 and is only valid in conjunction with the successful completion of the annual surveillance audits.

EU Certificate no.: 50593-60-00-02

Certificate valid from:

2025-01-13

Certificate valid to:

2025-12-13

Previous certificate no. 50593-60-00-01, issued on 2024-12-23



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de

BS-MDR-092

DEKRA Certification GmbH, Stuttgart
Notified Body ID number: 0124

Annex to the EU Certificate no. 50593-60-00-02

Following devices/device categories are included in this certificate:

Class IIa

MDA 0204 - Flexible sensor endoscopes

- Basic-UDI-DI: 405520717072019-0028786RR

Class I_r

For the devices listed below, the review of the quality management system refers exclusively to the aspects related to reuse, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

MDN 1208 - Trocar tips and obturators

- Basic-UDI-DI: 405520714102019-0018385CP

MDN 1208 - Working sleeves

- Basic-UDI-DI: 405520716102019-0017628FH

MDN 1208 – Sheaths, obturators and dilators

- Basic-UDI-DI: 405520711112019-001763092

MDN 1208 – Hand-held instruments

- Basic-UDI-DI: 405520724062021-0037381G3
- Basic-UDI-DI: 405520717012019-0018005FT
- Basic-UDI-DI: 405520706022019-0018176EU
- Basic-UDI-DI: 405520724062021-0037382G5

Change(s) to previous certificate:

- 50593-TD3-03 Addition of Trocar stylets and obturators (class I_r)
- 50593-CN24-18 Adjustment of wording to Flexible Sensor Endoscopes (class IIa)
- 50593-CN24-19 Extension to include reusable products (class I_r)
- 50593-CN24-21 Extension to include reusable products (class I_r)
- Adjustment of wording of above mentioned changes