

# 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 CNo50593-01 and is only valid in conjunction with the successful completion of the annual surveillance audits.

EU Certificate no.: 50593-60-01-01

Certificate valid from:

2025-12-17

Certificate valid to:

2030-12-13

Previous certificate no. 50593-60-01-00, issued on 2025-12-11

DEKRA Certification GmbH, Stuttgart  
Notified Body ID number: 0124



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)

BS-MDR-092

# Annex to the EU Certificate no. 50593-60-01-01

Following devices/device categories are included in this certificate:

## Class Ir

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

MDN 1208 - Suture instruments  
- Basic-UDI-DI: 405520714012019-0017764CS

## Class IIb

MDA 0306 - Insufflators  
- Basic-UDI-DI: 405520731102025-0039821AH  
Intended Use: The products are used to insufflate CO<sub>2</sub> in body cavities or hollow organs

- Basic-UDI-DI: 405520731102025-0039822AK  
Intended Use: The products are used for insufflation of CO<sub>2</sub> into body cavities or hollow organs as well as to discharge the insufflation gas.

- Basic-UDI-DI: 405520731102025-0039823AM  
Intended Use: The products are used for insufflation of CO<sub>2</sub> into body cavities or hollow organs and to heat CO<sub>2</sub> in body cavities or hollow organs.

- Basic-UDI-DI: 405520731102025-0039824AP  
Intended Use: The products are used for insufflation of CO<sub>2</sub> into body cavities and/or hollow organs, to heat CO<sub>2</sub> in body cavities or hollow organs and to discharge the insufflation gas.

Change(s) to previous certificate:  
Implementation products under MDA 0306 / Class IIb