

CERTIFICATE

Number: 2238851

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Richard Wolf GmbH

Pforzheimer Str. 32
75438 Knittlingen
Germany

Manufacturer Facility Identifier F001482

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA n. 665/2022, 551/2021 and 67/2009
Canada: Medical Devices Regulations - Part 1- SOR 98/282
Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68 and PMD Act
United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

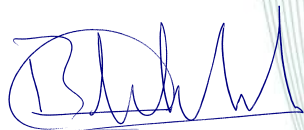
Scope:

Design and development, production, distribution, installation and service of systems, active medical devices (sterile, non-sterile), non-active medical devices (sterile, non-sterile) for human medicine, in particular for endoscopy and extracorporeal shockwave application.
Design and development, production, and distribution of non-active implants in urology and surgery as well as accessories for processing (cleaning, disinfection, sterilization).

Certificate expiry date: 2025-07-01
Certificate effective date: 2023-07-01
Certified since: 2019-07-11

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.M.A. McKenzie
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
<https://www.dekra-product-safety.com/en/certified-organizations>

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.



ADDENDUM

To certificate: 2238851

The management system of the organization(s) and/or location(s) of:

Richard Wolf GmbH

Pforzheimer Str. 32
75438 Knittlingen
Germany

Certified organization(s) and/or locations:

Different scope

Richard Wolf GmbH
Reuchlinstr. 10-11
10553 Berlin
Germany
Facility Identifier F002288

Manufacture of flexible and rigid endoscopes.

Addendum expiry date: 2025-07-01

Addendum effective date: 2023-07-01