

# CERTIFICATE



## EN ISO 13485:2016 + AC:2018 + A11:2021

DEKRA Certification GmbH hereby certifies that the organization

**Richard Wolf GmbH**

### Scope of certification:

Design and development, manufacture, distribution, installation and maintenance of systems, active medical devices (sterile, non-sterile) and non-active medical devices (sterile, non-sterile) for human medicine in the diagnosis and therapy of the following minimally invasive and non-invasive disciplines:

- Visceral surgery
- Gynecology
- Pulmonology/thoracic surgery
- Urology
- Orthopedics
- Proctology
- Spinal surgery
- Extracorporeal shockwave therapy and shockwave lithotripsy

using the following devices:

- Electrosurgical instruments and generators
- Motor drive devices
- Imaging devices
- Illumination devices
- Insufflators and instruments
- Pumps
- Device carts
- Suction/irrigation instruments (sterile/non-sterile)
- Aiming devices for orthopedics
- Access instruments
- Endoscopes flexible/rigid (sterile/non-sterile)
- Suture instruments
- Manual surgical instruments (sterile/non-sterile)
- Laser devices and instruments
- Systems/devices for Extracorporeal Shockwave Lithotripsy (ESWL)
- Devices for Extracorporeal Shockwave Therapy (ESWT)
- Software for Medical Device Control, data storage, data management and data routing

Certificate registration no.: 50593-21-01 valid from 2024-11-29 to 2027-11-28

# Certificate No. 50593-21-01



## Continuation of scope of certification:

Design and development, manufacture, and distribution of non-active implants in transanal endoscopic microsurgery as well as non-active medical products for cleaning, disinfection, sterilization, service, maintenance, reprocessing, storage and transport

- Non-active implants and applicators
- Products for cleaning, disinfection, sterilization, service, maintenance, reprocessing, storage and transport

## Certified location:

Pforzheimer Str. 32, 75438 Knittlingen, Germany  
(further locations see annex)

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 50593-R5-00.

Certificate registration no.: 50593-21-01\_EN  
Validity of previous certificate: 2024-11-28

Certificate valid from: 2024-11-29  
Certificate valid to: 2027-11-28

  
Markus Kopf  
DEKRA Certification GmbH, Stuttgart, 2024-11-25




# Annex to the Certificate No. 50593-21-01

valid from 2024-11-29 to 2027-11-28

The following locations/companies belong to the certificate above:

	Headquarters	Certified location	Scope of certification
	Richard Wolf GmbH	Pforzheimer Str. 32 75438 Knittlingen Germany	see page 1
	<b>at the following locations/at the companies at the following locations</b>		<b>Scopes of certification</b>
1.		Reuchlinstr. 10-11 10553 Berlin Germany	Manufacture of flexible and rigid endoscopes



Markus Kopf  
DEKRA Certification GmbH, Stuttgart, 2024-11-25