EC CERTIFICATE

for the Quality Assurance System

according the Directive 93/42/EEC, Annex V

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

Richard Wolf GmbH

Pforzheimer Straße 32, 75438 Knittlingen, Germany

Certified location:

Pforzheimer Straße 32, 75438 Knittlingen, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex V for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50593-Z6-00, the decision dated 2017-05-17 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2017-05-17 to 2020-05-16

Registration No.: 50593-17-03

DEKRA Certification GmbH * Stuttgart * Handwerkstraße 15 * D-70565

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2017-05-17
Notified Body ID-number: 0124

Annex to the EC Certificate No. 50593-17-03

Revision status: 0

Valid from 2017-05-17 to 2020-05-16

Devices/device categories included in the certificate:

Class I s:

For the products listed below, review of the Quality Assurance System refers exclusively to aspects of manufacture concerned with securing and maintaining sterile conditions.

- Endoscope assembly adaptor
- Endoscope inflation bulb
- Flexible bronchoscopic biopsy forceps, reusable
- Flexible endoscopic cytology brush, single-use
- General-purpose ureteral catheter
- Proctoscope, single-use
- Rigid endoscope sheath
- Ureteropelvic balloon catheter
- Urinary stone retrieval basket, single-use

Class II a:

- Catheter introducer
- Endoscopic antifog solution
- Endoscopic needle, general-purpose, single-use
- Flexible bronchoscopic biopsy forceps, reusable
- General-purpose non-vascular guidewire

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