EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60151129 0001

Report No.: 21232416 020

Manufacturer:
Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Deutschland

Products:
medical endoscopy, surgical, diagnostic, and treatment systems

(see attachment for products and sites included)

Replaces Approval, Registration No.: HD 60104211 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-08-12

Date: 2020-08-12

Notified Body

Roland Gruber

TÜV Rheinland LGA Products GmbH

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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Doc. 1/3, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60151129 0001
Report No.: 21232416 020

Manufacturer: Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Deutschland

Products included:

- Telescopes, Videoscopes and Fiberscopes
- Electrosurgical Instruments
- Electrosurgical Forceps
- Electrosurgical Hand Pieces
- Electrosurgical Units
- Electrosurgical Electrodes
- Electrosurgical Cables and Adapters, Active Cords
- Peristaltic Pump Units
- Peristaltic Tubing Sets
- Invasive Access Devices
  (which would encompass obturators, sheaths, trocars, bridges and irrigation ports)
- Endoscopy Instruments
  (which would encompass cannulas, injection needles, ballon dilators, adaptors, tubes and non-active instruments)

Notified Body

Date: 2020-08-12

Roland Gruber

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60151129 0001
Report No.: 21232416 020

Manufacturer: Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Deutschland

Products included:

- Working Elements and Inserts
- Bladder Syringes
- Washer-Disinfectors
- Adaptors for Washer-Disinfectors
- Fluid Management Systems used in Endoscopy
- Light Sources

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- sterile Caps

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TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

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TÜV Rheinland
LGA Products GmbH
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Attachment to Certificate
Registration No.: HD 60151129 0001
Report No.: 21232416 020

Manufacturer: Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Deutschland

Sites included:

Olympus Winter & Ibe GmbH
Rheinstr. 8
14513 Teltow
Germany

- Design and development, manufacturing of medical devices for electrosurgery and for endoscopic applications

Notified Body

Date: 2020-08-12

Roland Gruber

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle