EC Certificate

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

Registration No.: HD 60139275 0001

Report No.: 21250618 017

Manufacturer:
W.O.M. World of Medicine GmbH
Salzufer 8
10587 Berlin
Deutschland

Products: see attachment for products included

Replaces EC Certificate, Registration No.: HD 60112949 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: 2019-08-21

Date: 2019-08-21

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Dipl.-Ing. F. Bley

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.

Signature Not Verified
Dokument podpisany przez Małgorzata Adamczyk
Data: 2022.06.24 15:49:25 CEST

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60139275 0001
Report No.: 21250618 017

Manufacturer: W.O.M. World of Medicine GmbH
Salzufer 8
10587 Berlin
Deutschland

Products included:

- Insufflators for Laparoscopy
- Irrigation Pumps for Arthroscopy
- Suction and Irrigation Pumps for Laparoscopy
- Irrigation Pumps for Hysteroscopy
- Multiindication Pumps
- Tube Sets for Insufflators, single-use
- Tube Sets for Insufflators, reusable
- Heating Tube Sets for Insufflators, reusable
- Inflow Tube Sets for Pumps, single-use
- Tube Sets for Pumps, reusable
- Endoscopic Vessel Harvesting Instruments

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

- Outflow Tube Sets for Pumps, single-use

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Notified Body

Date: 2019-08-21

Dipl.-Ing. F. Bley