TÜVRheinland®

EC Certificate

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

Registration No.: HD 60111728 0001

Report No.: 21246570 001

Manufacturer:
MELAG Medizintechnik oHG
Geneststr. 6-10
10829 Berlin
Deutschland

Products:
- Active devices for disinfection and sterilization
- Non active medical devices for disinfection, cleaning and rinsing

(see attachment for products included)

Expiry Date: 2021-06-30

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: 2016-07-01

Date: 2016-06-23

Notified Body

Dipl.-Ing. D. Meier

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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TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60111728 0001
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Product groups included:

Premium-Plus-Klasse
Profi-Klasse
S-Klasse
MELAtronic
Cliniklav
Cliniclave
MELAquick
MELAtherm
MELAclean
MELAdes

Date: 2016-06-23

Notified Body

Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Dipl.-Ing. D. Meier