EC Certificate

TÜVRheinland®

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

Digitally signed by Ceaicovschi Tudor
Date: 2021.05.27 15:49:21 EEST
Reason: MoldSign Signature
Location: Moldova

Registration No.: HD 1082891-1

Manufacturer: MELAG Medizintechnik GmbH & Co. KG
Geneststr. 6-10
10829 Berlin
Germany

Products: Active devices for disinfection and sterilization

Product groups included:

- Careclave
- Cliniclave
- MELAtronic
- MELAquick
- MELAtherm 10
- Premium-Plus-Class
- Pro-Class
- S-Class

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.

Report No.: 3327953-90

Effective date: 2021-01-28

Expiry date: 2024-05-26

Issue date: 2021-01-28

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Dipl.-Ing. A. Fechner
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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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The scope of certification includes the following manufacturing sites:

No.	Location	Scope
/01	MELAG Medizintechnik GmbH & Co. KG Geneststr. 6-10 10829 Berlin Germany	Design/development and manufacture
/02	MELAG Medizintechnik GmbH & Co. KG Geneststr. 2 10829 Berlin Germany	Design/development and manufacture

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