

EC Certificate

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

Registration No.: HD 60147132 0001

Report No.:

21246570 016

lanufacturer:

MELAG Medizintechnik GmbH & Co. KG

Geneststr. 6-10 10829 Berlin Deutschland

roducts:

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

(see attachment for sites and product groups included) Replaces EC Certificate, Registration No.: HD 60143267 0001

xpiry Date:

2024-05-26

he Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 3/42/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 his certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date:

2020-02-25

)ate:

2020-02-25

TBY TUEV and TUV are registered makes. Utilisation and spracetor registes prior to

Notified Body

Dipl.-Ing. A. Fech

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.



TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 1/2, Rev. 0

Attachment to Certificate

Registration No.:

HD 60147132 0001

Report No.:

21246570 016

Manufacturer:

MELAG Medizintechnik GmbH & Co. KG

Geneststr. 6-10 10829 Berlin Deutschland

Site included:

MELAG Medinzintechnik GmbH & Co. KG Geneststraße 2 10829 Berlin Germany

Date: 2020-02-25

Notified Body

Myla Full Tovrhainsend

Dipl.-Ing. A. Fechner



TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev. 0

Attachment to Certificate

Registration No.:

HD 60147132 0001

Report No.:

21246570 016

Manufacturer:

MELAG Medizintechnik GmbH & Co. KG

Geneststr. 6-10 10829 Berlin Deutschland

Product groups included:

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

Date: 2020-02-25

Notified Body

Aula Fully

Dipl.-Ing. A. Fechner