EC Certificate

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

Registration No.: HD 60142289 0001

Report No.: 21217788 015

Manufacturer:
DMB Apparatebau GmbH
Spiesheimer Weg 25 a
55286 Wörrstadt
Deutschland

Products: fully automatic low temperature ethylene oxide sterilizers

Replaces Certificate, Registration No.: HD 60097139 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: 2019-08-27

Date: 2019-08-27

Notified Body

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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.