

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb or III)

No. G1 14 12 89139 002

Manufacturer: Cilag GmbH International

Advanced Sterilization Products

Gubelstrasse 34

6300 Zug

SWITZERLAND

Facility(ies): Cilag GmbH International Advanced Sterilization Products

Gubelstrasse 34, 6300 Zug, SWITZERLAND

Product

Biocide-based disinfectants for use with invasive medical devices and Category(ies):

accessories

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713045076

2015-04-07 Valid from: Valid until:

2020-04-06

Date, 2015-04-10

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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