EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60127175 0001

Report No.: 21186871 014

Manufacturer:
Hager & Werken GmbH & Co. KG
Ackerstr. 1
47269 Duisburg
Deutschland

Products: Dental devices

(see attachment for products included)

Replaces Certificate, Registration No.: DD 60119143 0001

Expiry Date: 2023-02-19

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2018-02-26

Date: 2018-02-26

Notified Body

Dr. K. Kluge

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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Doc. 1/1, Rev. 1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60127175 0001
Report No.: 21186871 017

Manufacturer: Hager & Werken GmbH & Co. KG
Ackerstr. 1
47269 Duisburg
Deutschland

Products included:

- Rotating instruments
- Material for tooth build-up
- Disinfectants
- Laser fibers

For the following devices the scope covers only the aspects of the manufacture concerned with the securing and maintaining sterile conditions:

- Sterile dental instruments

for
Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2018-10-24

Dipl.-Ing. I. Munkler