

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

Registration No.: HD 60127176 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.: HD 60093497 0001

Expiry Date: 2023-02-19

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: 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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60127176 0001
Report No.: 21186871 017

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

Products included

- Root canal anchors
- Rotating instruments
- Material for tooth build-up
- Injection needles for dentistry
- Splinting and fixation materials
- Tissue adhesive
- Dental handpieces
- Application needles for dentistry
- Nutrient solution for tooth preservation
- High frequency surgical equipment

Date: 2018-10-22


Notified Body

Dipl.-Ing. I. Munkler

