



**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.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** DD 60127175 0001  
**Report No.:** 21186871 017

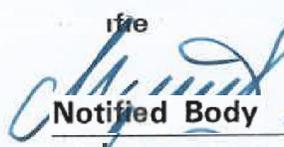
**Manufacturer:** Hager & Werken GmbH & Co. KG  
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47269 Duisburg  
Deutschland

**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

  
**Notified Body**  
  
TÜV Rheinland LGA Products GmbH  
TÜVRheinland  
Vertretungsstelle

**Date:** 2018-10-24

**Dipl.-Ing. I. Munkler**