EC Certificate

TÜVRheinland®

Production Quality Assurance
MDD Annex V

Registration No.: DD 1011605-1

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

Products: Dentalprodukte

Ersetzt Zertifikat, Registrier-Nr.: DD 60149479 0001

Einbezogene Produkte:

- Rotierende Instrumente
- Material für den Zahnaufbau
- Desinfektionsmittel
- Laserfasern

Für folgende Produkte bezieht sich der Geltungsbereich ausschließlich auf die Herstellungsschritte im Zusammenhang mit der Sterilisation und der Aufrechterhaltung der Sterilität:

- sterile Dentalinstrumente

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.

Report No.: 3348353-40

Effective date: 15.02.2021

Expiry date: 26.05.2024

Issue date: 15.02.2021

TÜV Rheinland LGA Products GmbH TÜVRheinland

Dr. K. Kluge
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Deutschland

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

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Production Quality Assurance
MDD Annex V

Registration No.: DD 1011605-1

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

Products: Dental devices

Replaces Certificate, Registration No.: DD 60149479 0001

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

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.

Report No.: 3348353-40

Effective date: 2021-02-15

Expiry date: 2024-05-26

Issue date: 2021-02-15

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Dr. K. Kluge
TÜV Rheinland LGA Products GmbH
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