

EC Certificate

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

Registration No.: DD 1354467-1

Manufacturer: Emil Lange
Zahnbohrerfabrik e.K.
Lepestr. 62
51766 Engelskirchen
Germany

Products: Manufacture of rotary instruments for dentistry

Products included:

- Carbide burs and finishers
- Steel burs and finishers
- Surgical burs and cutters
- Root canal instruments
- Diamond 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.: 3337424-30
Effective date: 2021-04-13
Expiry date: 2024-05-26
Issue date: 2021-04-13



Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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