

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V (Devices in Class IIa, IIb or III)

No. G2 15 07 40454 014

Manufacturer: SHERA Werkstoff-Technologie

GmbH & Co. KG

Espohlstraße 53 49448 Lemförde GERMANY

Facility(ies): SHERA Werkstoff-Technologie GmbH & Co. KG

Espohlstraße 53, 49448 Lemförde, GERMANY

Product - Dental casting and ceramic bonding alloys for

Category(ies): fixed and removable prostheses

- Dental acrylics for fixed and removable prostheses

- Ceramic dental materials for fixed and removable

prostheses

- Disinfectants for non-invasive medical devices

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: 713065861

Valid from: 2015-11-04

Valid until: 2020-11-03

H.- N.

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Date.

2015-08-27