EC CERTIFICATE

for the Quality Assurance System

according the directive 93/42/EEC, Annex II excluding section (4)

As a notified body of the European Union, DEKRA Certification GmbH certifies, that the company

VITA Zahnfabrik, H. Rauter GmbH & Co.KG

Spitalgasse 3, 79713 Bad Säckingen, Germany

applies a quality assurance system for the medical devices listed in the annex according to the directive 93/42/EEC annex II. The approval is based on the result of the re-certification audit report no. 50069-Z5-00, the decision dated 2016-05-26 is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2016-06-29 to 2019-06-28

Certificate registration No.: 50069-16-05

DEKRA Certification GmbH Stuttgart; 2016-05-26
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Annex to the EC Certificate 50069-16-05 dated 2016-05-26

DEKRA Certification GmbH · D-70565 Stuttgart, Handwerkstraße 15 ·

Devices/device categories included in the certificate

Class II a:

Artificial Teeth
(Removable and fixed artificial Teeth)

- Polymer Teeth
- Ceramic Teeth

CAD/CAM-Materials
(for crowns, bridges, inlays, onlays, veneers)

- Ceramic
- Hybrid-Material
- Polymer

Veneering Material
(Veneering material for metal and all-ceramics restorations)

- Polymer
- Ceramic

Accessory

- Accessory products and material for the dental laboratory and dental practice

Class II b:

Ceramic-dental implants

Class I s:

For the products listed below, review of the Quality Assurance System refers exclusively to aspects of manufacturing steps concerned with assuring and maintaining sterile conditions.
Impression tool for dental implants