Annex to the EC Certificate No. 50069-16-06

Valid from 2019-06-29 to 2024-05-26

Revision status of the annex: 0 dated 2019-06-29

Devices/device categories included in the certificate:

Class I s:

For the products listed below, review of the Quality Assurance System refers exclusively to aspects of manufacture concerned with securing and maintaining sterile conditions.

Impression tool for dental implants

Class II a:

Artificial Teeth
(Removable and fixed artificial Teeth)

- Polymer Teeth
- Ceramic Teeth

CAD/CAM Materials
(For crowns, brides, inlays, onlays, veneers and dentures)

Veneering Materials
(Veneering materials for metal and all-ceramics restorations)

- Polymer
- Ceramic

Accessory

- Accessory Products and material for the dental laboratory and dental practice
- Dentale Adhesive

Class II b:

Ceramic-dental implants

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2019-06-14
Notified Body ID-number: 0124

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

Certified location:

Spitalgasse 3, 79713 Bad Säckingen, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50069-Z6-00, the decision dated 2019-06-14 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2019-06-29 to 2024-05-26

Registration No.: 50069-16-06

DEKRA

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-06-14
Notified Body ID-number: 0124

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