

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
Omnident Dental-Handelsgesellschaft mbH

Gutenbergring 5, 63110 Rodgau, Germany

Certified location:

Gutenbergring 5, 63110 Rodgau, 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. 50151-Z6-00, the decision dated 2019-03-13 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2019-03-24 to 2024-03-23

Registration No.: 50151-16-05



Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-03-13
Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de



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 No. 50151-16-05

Valid from 2019-03-24 to 2024-03-23

Revision status of the annex: 0 dated 2019-03-24

Devices/device categories included in the certificate:

Class II b:

- MD 0108
 - Disinfection for medical devices
 - Omnisept Plus



A handwritten signature in black ink, appearing to read "Ruth", is written over a horizontal line.



Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2019-03-13
Notified Body ID-number: 0124

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