

EC CERTIFICATE

for the Quality Assurance System



according the directive 93/42/EEC, Annex V

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

Omnident Dental-Handelsgesellschaft mbH

Gutenbergring 7-9, 63110 Rodgau, Germany

applies a quality assurance system for the medical devices listed in the annex according to the directive 93/42/EEC annex V. The approval is based on the result of the re-certification audit report no. 50151-Z5-00, the decision dated 2016-03-23 is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2016-03-24 to 2019-03-23

Certificate registration No.: 50151-17-05



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

ZLG-BS-295.10.02

DEKRA Certification GmbH Stuttgart; 2016-03-23

Notified Body ID-number: 0124

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

Annex to the EC Certificate 50151-17-05 dated 2016-03-23

Revision status: 1

Date: 2016-05-12

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Devices/device categories included in the certificate

Klasse IIa:

- MD 0102
 - Disposables
 - Injection needles Omniject
 - Smartdent injection needles
- MD 0108
 - Disinfection
 - Omniwipes
 - Omniwipes Floor
 - Omniwipes wet & easy
 - Omniwipes Wet Fleur
 - Omnizid
 - Omnipur
 - Omnibiozid
 - Omnisuc
 - Salivasept
 - Saliva Nanosept
 - Omnissept IMP
 - Smartdent soaked disinfection wipes
- MD 0401
 - Rotating instruments (dental)
 - Omnicut
 - Omni Multicut
 - Omnigloss
 - Omnipol
 - Omniround
 - Omni Diamant FG
 - Endodontia
 - Gutta-percha points
 - Paper points
 - Disposables
 - Saliva ejector
- MD 0402
 - Temporary care
 - Magic-Crowns
 - Omnifill
 - Omnitemp
 - Prophylaxis
 - Omniflow
 - Omniflow Soft
 - Omniflow PERIO pro
 - Omniwhite smile
 - Omni Minibrush
 - Omni tips
 - Omni ProfiCups
 - Permanent Care
 - OmniCeram
 - OmniCeram évolution
 - OmniCeram évolution flow
 - OmniCite
 - OmniCite Etch'n'Bond
 - Omni Compomer
 - OmniCite All'N'One
 - OmniCeram Bulk Fill
 - Adjuvant for fillings
 - Omnipin
 - Omnni-Etch

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