

# 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 5, 63110 Rodgau, Germany

**Certified location:**

Gutenbergring 5, 63110 Rodgau, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex V 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.: 50151-17-06

A handwritten signature in black ink, appearing to read 'Ruth Delbeck-Bayer', written over a horizontal line.



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



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
**ZLG-BS-295.10.02**



# Annex to the EC Certificate No. 50151-17-06

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 a:

- MD 0102
  - Disposables
    - Injection needles Omniject
    - Smartdent injection needles
- MD 0108
  - Disinfection
    - Omnizid
- MD 0401
  - Rotating instruments (dental)
    - Omnipol Amalgam Reducer
    - Omnipol CeraGloss
    - Omnipol (brown/green)
  - Endodontia
    - Omni Guttapercha points
    - Omni Paper points
  - Disposables
    - Omnident saliva ejector
    - Salvia ejector (smart)
- MD 0402
  - Temporary care
    - Omnifill C
    - Omnitemp C / KB
  - Prophylaxis
    - Omniflow
    - Omniflow Soft
    - Omniflow PERIO pro
    - Omni tips
    - Omni ProfiCups (blue/yellow)
  - Permanent Care
    - OmniCeram évolution
    - OmniCeram évolution flow
    - OmniCite
    - Omni Compomer
    - OmniCeram Bulk Fill





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