

CERTIFICATE

for the

Quality Assurance System



As a notified body of the European Union (Reg. No. 0124) DEKRA Certification GmbH hereby approves the Quality Assurance System applied for manufacture and final inspection by the company

OMNIDENT Dental-Handelsgesellschaft mbH
Gutenbergring 7-9 • 63110 Rodgau, Germany

Approval is based on the decision dated 21.03.2011 and the result of the report no. 50151-Z4-00 and is performed in accordance with the stipulations of

Annex V, Section 3 of the Directive 93/42/EEC

of the Council dated June 14, 1993 governing medical devices. The certification is applicable to the devices specified in the Annex. The devices in question are subjected to testing and examination in accordance with Annex V, Section 3 of the Directive 93/42/EEC. The listed devices may be affixed with the CE marking indicated below.



Date of the first certification: 14.02.1997

This certificate is valid until: 23.03.2016

Date of the last recertification: 24.03.2011

Certificate-registration No.: 50151-17-04
English version

DEKRA Certification GmbH
Stuttgart, 21.03.2011



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-992.94.16

Annex to the Certificate 50151-17-04 dated 21.03.2011

English version

Revision status: 4

Date: 22.07.2015

Page 1 of 2

Devices/device categories included in the certificate

Class II a:

Disinfection

- Omniwipes (Disinfection for medical devices)
- Omniwipes wet & easy (Disinfection for medical devices)
- Omniwipes Wet Fleur (Disinfection for medical devices)
- Omnizid (Disinfection for medical devices)
- Omnipur (Disinfection for medical devices)
- Omnibiozid (Disinfection for medical devices)
- Omnisuc (Disinfection for medical devices)
- Salivasept (Disinfection for medical devices)
- Saliva Nanosept (Disinfection for medical devices)
- Omnisept IMP (Disinfection for medical devices)
- smartdent soaked disinfection wipes

Disposables

- Injection needles
- smartdent injection needles

Temporary Care

- Magic-Crowns (Temporary polycarbonate crowns)
- Omnifill (Condensable restorative cement)
- Omnitemp (Temporary crown- and bridge material)

Adjuvant for fillings

- Omnipin (Parapulpal retention pins)
- Omni-Etch (Etching gel)

Rotating instruments (dental):

- Omnicut
- Omni Multicut
- Omnigloss
- Omnipol
- Omniround
- Omni Diamant FG

Endodontia:

- Gutta-percha points
- Paper points

Prophylaxis

- Omniflow (Prophylaxis blasting abrasive)
- Omniflow Soft (Prophylaxis blasting abrasive)
- Omniflow PERIO pro (Prophylaxis blasting abrasive)
- Omniwhite smile (Tooth whitening gel)
- Omni Minibrush (Prophylaxis polishing brushes)
- Omni tips (Scaler- & Perio instruments)
- Omni ProfiCups (Prophylaxis polishing brushes)



Annex to the Certificate 50151-17-04 dated 21.03.2011

English version

Revision status: 4

Date: 22.07.2015

Page 2 of 2



Devices/device categories included in the certificate

Class II a:

Permanent Care

- | | |
|----------------------------|--|
| - OmniCeram | (lightcuring hybrid-composite) |
| - OmniCeram évolution | (lightcuring nano-hybrid-composite) |
| - OmniCeram évolution flow | (lightcuring nano-hybrid-composite) |
| - OmniCite | (one-component lightcuring adhesive) |
| - OmniCite Etch'n'Bond | (two-component lightcuring adhesive) |
| - Omni Compomer | (lightcuring composite) |
| - OmniCite All'N'One | (one-component lightcuring adhesive) |
| - OmniCeram Bulk Fill | (lightcuring posterior filling material) |

Disposables

- | | |
|------------------|--------------|
| - Saliva ejector | (aspiration) |
|------------------|--------------|