

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 design, 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 II, 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 II, 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: 16.03.2010

This certificate is valid until: 23.03.2016

Date of the last recertification: 24.03.2011

Certificate-registration No.: 50151-16-01
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 50151-16-01 dated 21.03.2010

English version

Revision status: 0

Date: 24.03.2011

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Devices/device categories included in the certificate

Class II b:

Disinfection for medical devices

- Omnisep
- Omnidrill



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