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 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 II. 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.: 50151-16-04

DEKRA Certification GmbH Stuttgart; 2016-03-23
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

84460

Annex to the EC Certificate 50151-16-04 dated 2016-03-23

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15 •

Devices/device categories included in the certificate

Class II b:

- MD 0108
  - Disinfection for medical devices
    - Omnisept
    - Omnidrill
    - Omnisept Plus