

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60104785 0001

Report No.: 12031244 001

Manufacturer: Kuraray Noritake Dental Inc.
1621 Sakazu, Kurashiki
Okayama 710-0801
Japan

Products: Dental Materials
(see attachments for products and sites included)
Replaces Approval, Registration No.: HD 60078849 0001

Expiry Date: 2020-10-29

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2016-07-28

Date: 2016-07-28



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.