

EC Certificate

Full Quality Assurance System MDD Annex II excl. 4

Registration No.: HD 2094592-1

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

Products: Dental Materials

Products included:

- Dental Etching Liquids
- Dental Porcelain Repair Kits
- Dental Other Restorative Materials
- Dental Composite Restorative Material Kits
- Dental Composite Restorative Materials
- Dental Resin Composite Cement
- Dental Unfilled Restorative Materials
- Dental Crown and Bridge Restorative Materials
- Orthodontic Cement
- Dyes, Dental Caries Detection
- Dental Posts, Endodontic
- Desensitizers

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.

Report No.: 1231244 015

Effective date: 2020-07-10

Expiry date: 2024-05-26

Issue date: 2020-07-11



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

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

No.	Location	Product groups manufactured
/01	Kuraray Noritake Dental Inc., Niigata Plant 2-28 Kurashiki-cho, Tainai, Niigata 959-2653 Japan	Dental Materials Products included: - Dental Etching Liquids - Dental Porcelain Repair Kits - Dental Other Restorative Materials - Dental Composite Restorative Material Kits - Dental Composite Restorative Materials - Dental Resin Composite Cement - Dental Unfilled Restorative Materials - Dental Crown and Bridge Restorative Materials - Orthodontic Cement - Dyes, Dental Caries Detection - Dental Posts, Endodontic - Desensitizers

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

/02 Kuraray Noritake Dental Inc.,
Tokyo Office
1-1-3, Otemachi,
Chiyoda-ku, Tokyo,
100-0004 Japan

Dental Materials

Products included:

- Dental Etching Liquids
- Dental Porcelain Repair Kits
- Dental Other Restorative Materials
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- Dental Composite Restorative Materials
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