kuraray Noritake

# Declaration of Conformity

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|---|---|
| **Manufacturer's name** | : **Kuraray Noritake Dental Inc.** |
| **Manufacturer's address** | : **1621 Sakazu, Kurashiki, Okayama, 710-0801, Japan** |
| **European Representative's name** | **Kuraray Europe GmbH** |
| **European Representative's address** | **Philipp-Reis-Str.4,** |
| | **65795 Hattersheim am Main, Germany** |
| **Name of device** | : **CLEARFIL SE BOND 2** |
| **(Common name, Classification)** | **UMDNS: Dental Other Restorative Material [17-619]** |
| | **GMDN: Dentine bonding agent/set [34782]** |
| | **Classification: Class IIa (Rule 8)** |
| **Type, Model** | : **See attachment 1** |
| **Lot No.** | : **Covered after Declaration of Conformity as documented in the product release document for each batch** |
| **Initial manufacturing period** | : **2017-07** |

We herewith declare that the above mentioned product meets the provisions of the EC Directive 93/42/EEC which apply to it, as stated in Annex I of this directive.

This declaration is supported by:

**Standards applied**

: **EN 1641:2009, EN 1041:2008, ISO 780:2015, ISO 7405:2008, EN ISO 14971:2012, EN ISO 10993-1:2009, ISO 8601:2004, EN 980: 2008, ISO 15223-1:2016, EN 62366:2008**

**Approval of a quality system**

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| **Type of quality system** | : **EC Directive 93/42/EEC Annex II (Full Quality Assurance System)** |
| **Issued by** | : **TÜV Reinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg, Germany (Notified No. 0197)** |
| : | |
| **Place, date** | **Tokyo, 2017-06-30** |
| **Signature** | : 有川清之 |
| **Name** | : **Kiyoyuki Arikawa** |
| **Title** | : **President** |

Authorized Copy

Yasuyuki Ohara

Attachment 1

| Type | Product name |
|---|---|
| #3270-EU | CLEARFIL SE BOND 2 Kit |
| #3272-EU | CLEARFIL SE BOND 2 Value Pack |
| #3275-EU | CLEARFIL SE BOND 2 Trial Pack |
| #3281-EU | CLEARFIL SE BOND 2 BOND |
| #3282-EU | CLEARFIL SE BOND 2 PRIMER |
| #3286-EU | CLEARFIL SE BOND 2 Unit Dose Standard Pack |
| #3287-EU | CLEARFIL SE BOND 2 Unit Dose Trial Pack |