

Declaration of Conformity

Manufacturer's name	: Kuraray Noritake Dental Inc.
Manufacturer's address	: 1621 Sakazu, Kurashiki, Okayama, 710-0801, Japan
European Representative's name	EMERGO EUROPE
European Representative's address	Prinsessegracht 20 2514 AP The Hague, The Netherlands
Name of device	: CLEARFIL SE BOND 2
(Common name, Classification)	UMDNS: Dental Materials, Restorative [16188] 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	: 2021-11

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 7405:2018, EN ISO 14971:2012, EN ISO 10993-1:2009, ISO 10993-1:2018, ISO 8601-1:2019, ISO 8601-2:2019, ISO 15223-1:2016, EN 62366:2008, IEC 62366-1:2015, EN ISO 13485:2016/AC:2016

Approval of a quality system

Type of quality system : EC Directive 93/42/EEC Annex II (Full Quality Assurance System)
Conformity assessment route to Annex II, excluding section 4

Issued by : TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431 Nürnberg, Germany
(Notified No. 0197)

Place, date : Tokyo, 2021-09-02

Signature : 

Name : Satoshi Yamaguchi

Title : President

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

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