kuraray Noritake

EU Declaration of Conformity

Manufacturer's Name	: Kuraray Noritake Dental Inc.
Manufacturer's Address	: 1621 Sakazu, Kurashiki, Okayama, 710-0801, Japan
Manufacturer's SRN	: JP-MF-000017326
Authorized Representative's Name	: EMERGO EUROPE
Authorized Representative's Address	: Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands
Authorized Representative's SRN	: NL-AR-000000116
Product/Trade Name	: CLEARFIL Universal Bond Quick 2
Basic UDI-DI	: 458211076BondingHC
Product Code	: See attachment 1
Classification	: Class IIa (Rule 8)
Nomenclature	: EMDN: DENTAL RESTORATION DEVICES [Q010101] (DENTAL BONDING AGENTS [Q01010104]) GMDN: Dentine bonding agent/set [34782]
Intended purpose	: It is used as a bonding agent for dental restorations.
Common Specifications	: Not yet available
Conformity assessment route	: Kuraray Noritake Dental Inc. uses the following procedures for the CE-labeling of their Class IIa products according Regulation MDR 2017/745: conformity assessment according to Annex IX, Chapter I and III
Notified Body Name	: TÜV Rheinland LGA Products GmbH
Notified Body Address	: Tillystraße 2, 90431 Nürnberg, Germany
Notified Body Identification Number	: 0197
Notified Body Certificate Registration No.	: HZ 2094592-1
Initial manufacturing period	: 2025-01

This declaration of conformity is issued under the sole responsibility of Kuraray Noritake Dental Inc. We herewith declare that the above mentioned product is in conformity with the Regulation MDR 2017/745 on medical devices.

Standards applied:

EN 1641: 2009, EN ISO 20417: 2021, ISO 780: 2015, ISO 7405: 2018, EN ISO 14971: 2019, EN ISO 10993-1: 2020, EN ISO 10993-3: 2014, EN ISO 10993-5: 2009, EN ISO 10993-10: 2021, EN ISO 10993-11: 2018, EN ISO 10993-12: 2021, EN ISO 10993-23: 2021, ISO 8601-1: 2019, ISO 8601-2: 2019, EN ISO 15223-1: 2021, EN 62366-1: 2015+A1: 2020, EN ISO 13485: 2016+AC: 2018

Signature:

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Name: Satoshi Yamaguchi

Function: President of Kuraray Noritake Dental Inc.

Place and date of issue:

Tokyo, 2024-10-29

Attachment 1

Code	Product name
#4042-EU	CLEARFIL Universal Bond Quick 2 Bottle Refill
#4044-EU	CLEARFIL Universal Bond Quick 2 Bottle Value Pack
#4045-EU	CLEARFIL Universal Bond Quick 2 Bottle Trial
#4046-EU	CLEARFIL Universal Bond Quick 2 Unit Dose Standard Pack
#4048-EU	CLEARFIL Universal Bond Quick 2 Unit Dose Trial