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 MAJESTY ES Flow Universal
Basic UDI-DI	: 458211076CompositeKS
Product Code	: See attachment 1
Classification	: Class IIa (Rule 8)
Nomenclature	: EMDN: DENTAL RESTORATION DEVICES [Q010101] (DENTAL CONSERVATION COMPOSITES [Q01010103]) GMDN: Dental composite resin [35870]
Intended purpose	: It is used as a dental restorative material.
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 to 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	: 2025-1

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, ISO 10993-1: 2018, ISO 8601-1: 2019, ISO 8601-2: 2019, EN ISO 15223-1: 2021, ISO 4049:2019, EN 62366-1: 2015+A1: 2020, IEC 62366-1: 2015+A1: 2020, EN ISO 13485: 2016+AC: 2018

Signature:

Name: Satoshi Yamaguchi

Function: President of Kuraray Noritake Dental Inc.

Place and date of issue:

Tokyo, 2024- 09-30

Attachment 1

Code	Product name
#4600-EU	CLEARFIL MAJESTY ES Flow Universal Low (U)
#4601-EU	CLEARFIL MAJESTY ES Flow Universal Low (UD)
#4606-EU	CLEARFIL MAJESTY ES Flow Universal Low (U) TRIAL
#4609-EU	CLEARFIL MAJESTY ES Flow Universal Low (UD) TRIAL
#4620-EU	CLEARFIL MAJESTY ES Flow Universal Super Low (U)
#4621-EU	CLEARFIL MAJESTY ES Flow Universal Super Low (UD)
#4622-EU	CLEARFIL MAJESTY ES Flow Universal Super Low (U) TRIAL
#4623-EU	CLEARFIL MAJESTY ES Flow Universal Super Low (UD) TRIAL