

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	: KATANA AVENCIA Block 2
Basic UDI-DI	: 458211076BlockMH
Product Code	: See attachment 1
Classification	: Class IIa (Rule 8)
Nomenclature	: EMDN: DENTAL PROTHESES (Q010206) (COMBINED DENTAL PROTHESES (Q01020602)) GMDN: Dental Crown, Polymer [38595]
Intended purpose	: It is used for fabrication of dental restorations using a dental CAD/CAM system.
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	: 2025-08

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 8601-1: 2019, ISO 8601-2: 2019, EN ISO 15223-1: 2021, EN 62366-1: 2015/A1: 2020, EN ISO 13485: 2016+A11: 2021

Signature:



Name: Satoshi Yamaguchi

Function: President of Kuraray Noritake Dental Inc.

Place and date of issue:

Tokyo, 2025-06-05

Attachment 1

Code	Product name
#4151-EU	KATANA AVENCIA Block 2 12/A1 HT
#4152-EU	KATANA AVENCIA Block 2 12/A2 HT
#4153-EU	KATANA AVENCIA Block 2 12/A3 HT
#4154-EU	KATANA AVENCIA Block 2 12/A3.5 HT
#4156-EU	KATANA AVENCIA Block 2 14L/A1 HT
#4157-EU	KATANA AVENCIA Block 2 14L/A2 HT
#4158-EU	KATANA AVENCIA Block 2 14L/A3 HT
#4159-EU	KATANA AVENCIA Block 2 14L/A3.5 HT
#4166-EU	KATANA AVENCIA Block 2 12/A1 HT (CEREC)
#4167-EU	KATANA AVENCIA Block 2 12/A2 HT (CEREC)
#4168-EU	KATANA AVENCIA Block 2 12/A3 HT (CEREC)
#4169-EU	KATANA AVENCIA Block 2 12/A3.5 HT (CEREC)
#4171-EU	KATANA AVENCIA Block 2 14L/A1 HT (CEREC)
#4172-EU	KATANA AVENCIA Block 2 14L/A2 HT (CEREC)
#4173-EU	KATANA AVENCIA Block 2 14L/A3 HT (CEREC)
#4174-EU	KATANA AVENCIA Block 2 14L/A3.5 HT (CEREC)
#4181-EU	KATANA AVENCIA Block 2 14L/A1 ML
#4182-EU	KATANA AVENCIA Block 2 14L/A2 ML
#4183-EU	KATANA AVENCIA Block 2 14L/A3 ML
#4184-EU	KATANA AVENCIA Block 2 14L/A3.5 ML
#4186-EU	KATANA AVENCIA Block 2 14L/A1 ML (CEREC)
#4187-EU	KATANA AVENCIA Block 2 14L/A2 ML (CEREC)
#4188-EU	KATANA AVENCIA Block 2 14L/A3 ML (CEREC)
#4189-EU	KATANA AVENCIA Block 2 14L/A3.5 ML (CEREC)