



TÜV Rheinland LGA Products GmbH • 51105 Köln

Kuraray Noritake Dental Inc.
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JAPAN

Contact

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Date April 01, 2024

Notified Body Confirmation Letter

Reference. : KND_CL607_2024-04-01

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Kuraray Noritake Dental Inc.
1621 Sakazu, Kurashiki,
710-0801, Okayama
JAPAN
SRN Number: JP-MF-000017326

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function

On behalf of the Notified Body

Michiaki Aihara
Certification body

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Chairman of the
Supervisory Board

Dr.-Ing. Michael Fübi

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
PANAVIA SA Cement Universal	IIa	N/A	HD 2094592-1 #0197
KATANA Cleaner	IIa	N/A	HD 2094592-1 #0197
CLEARFIL SE Protect	III	N/A	HD 2094592-1 #0197 ID 60147083 0001 #0197
CLEARFIL F II NEW BOND	IIa	N/A	HD 2094592-1 #0197
CLEARFIL CORE NEW BOND	IIa	N/A	HD 2094592-1 #0197
CLEARFIL ST OPAQUER	IIa	N/A	HD 2094592-1 #0197
CLEARFIL PHOTO POSTERIOR	IIa	N/A	HD 2094592-1 #0197
CLEARFIL AP-X	IIa	N/A	HD 2094592-1 #0197
CLEARFIL PHOTO CORE	IIa	N/A	HD 2094592-1 #0197
K-ETCHANT GEL	IIa	N/A	HD 2094592-1 #0197
CLEARFIL NEW BOND	IIa	N/A	HD 2094592-1 #0197
CLEARFIL PHOTO BOND	IIa	N/A	HD 2094592-1 #0197
CLEARFIL PORCELAIN BOND ACTIVATOR	IIa	N/A	HD 2094592-1 #0197
CARIES DETECTOR	IIa	N/A	HD 2094592-1 #0197
PANAVIA 21	IIa	N/A	HD 2094592-1 #0197
ALLOY PRIMER	IIa	N/A	HD 2094592-1 #0197
CLEARFIL LINER BOND 2V	IIa	N/A	HD 2094592-1 #0197
CLEARFIL SE BOND	IIa	N/A	HD 2094592-1 #0197
CLEARFIL REPAIR	IIa	N/A	HD 2094592-1 #0197
CLEARFIL SA PRIMER	IIa	N/A	HD 2094592-1 #0197
CLEARFIL AP-X PLT	IIa	N/A	HD 2094592-1 #0197
PANAVIA F 2.0	IIa	N/A	HD 2094592-1 #0197
CLEARFIL PHOTO CORE PLT	IIa	N/A	HD 2094592-1 #0197
CLEARFIL MAJESTY Posterior	IIa	N/A	HD 2094592-1 #0197
CLEARFIL MAJESTY Esthetic	IIa	N/A	HD 2094592-1 #0197
CLEARFIL MAJESTY Flow	IIa	N/A	HD 2094592-1 #0197
CLEARFIL MAJESTY Posterior PLT	IIa	N/A	HD 2094592-1 #0197
CLEARFIL PHOTO BRIGHT	IIa	N/A	HD 2094592-1 #0197
CLEARFIL DC CORE PLUS	IIa	N/A	HD 2094592-1 #0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
TEETHMATE DESENSITIZER	Ila	N/A	HD 2094592-1 #0197
CLEARFIL MAJESTY ES Flow	Ila	N/A	HD 2094592-1 #0197
CLEARFIL MAJESTY ES-2	Ila	N/A	HD 2094592-1 #0197
CLEARFIL Performance Pro	Ila	N/A	HD 2094592-1 #0197
CLEARFIL LINER BOND F	Ila	N/A	HD 2094592-1 #0197
CLEARFIL TRI-S BOND Universal	Ila	N/A	HD 2094592-1 #0197
CLEARFIL SE BOND 2	Ila	N/A	HD 2094592-1 #0197
CLEARFIL DC Activator	Ila	N/A	HD 2094592-1 #0197
K-ETCHANT Syringe	Ila	N/A	HD 2094592-1 #0197
CLEARFIL TRI-S BOND Universal Kit	Ila	N/A	HD 2094592-1 #0197
KATANA AVENCIA Block	Ila	N/A	HD 2094592-1 #0197
PANAVIA V5	Ila	N/A	HD 2094592-1 #0197
CLEARFIL CERAMIC PRIMER PLUS	Ila	N/A	HD 2094592-1 #0197
CLEARFIL Universal Bond Quick	Ila	N/A	HD 2094592-1 #0197
CLEARFIL DC CORE PLUS & Quick KIT	Ila	N/A	HD 2094592-1 #0197
PANAVIA Veneer LC	Ila	N/A	HD 2094592-1 #0197

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-04-01	KND_CL607_2024-04-01	Initial issue