kuraray Noritake

Declaration of Conformity

Manufacturer's name	: Kuraray Noritake Dental Inc.
Manufacturer's address	: 1621 Sakazu, Kurashiki, Okayama, 710-0801, Japan
European Representative's name	Kuraray Europe GmbH
European Representative's address	Philipp-Reis-Str.4, 65795 Hattersheim am Main, Germany
Name of device	: PANAVIA SA Cement Universal
(Common name, Classification)	UMDNS: Dental Materials, Cement, Resin Composite [16707] GMDN: Dental composite resin [35870] 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	: 2020-10

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 Reinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg, Germany (Notified No. 0197)

Place, date : Tokyo, 2020-10-19

Signature :

Name : Kiyoyuki Arikawa

Title : President

Attachment 1

Type	Product name
#4202-EU	PANAVIA SA Cement Universal Handmix (Universal (A2))
#4203-EU	PANAVIA SA Cement Universal Handmix (White)
#4204-EU	PANAVIA SA Cement Universal Handmix (Translucent)
#4206-EU	PANAVIA SA Cement Universal Handmix Double Pack (Universal(A2))
#4207-EU	PANAVIA SA Cement Universal Handmix Trial (Universal(A2))
#4210-EU	PANAVIA SA Cement Universal Automix Value Pack (Universal(A2))
#4211-EU	PANAVIA SA Cement Universal Automix Value Pack (Translucent)
#4212-EU	PANAVIA SA Cement Universal Automix (Universal (A2))
#4213-EU	PANAVIA SA Cement Universal Automix (White)
#4214-EU	PANAVIA SA Cement Universal Automix (Translucent)
#4216-EU	PANAVIA SA Cement Universal Automix Trial (Universal(A2))
#4217-EU	PANAVIA SA Cement Universal Automix Trial (Translucent)
#4218-EU	PANAVIA SA Cement Universal Automix Mixing tip
#4221-EU	PANAVIA SA Cement Universal Automix Endo tip (SS)

Type	Product name
#4202-UK	PANAVIA SA Cement Universal Handmix (Universal (A2))
#4203-UK	PANAVIA SA Cement Universal Handmix (White)
#4204-UK	PANAVIA SA Cement Universal Handmix (Translucent)
#4206-UK	PANAVIA SA Cement Universal Handmix Double Pack (Universal(A2))
#4207-UK	PANAVIA SA Cement Universal Handmix Trial (Universal(A2))
#4210-UK	PANAVIA SA Cement Universal Automix Value Pack (Universal(A2))
#4211-UK	PANAVIA SA Cement Universal Automix Value Pack (Translucent)
#4212-UK	PANAVIA SA Cement Universal Automix (Universal (A2))
#4213-UK	PANAVIA SA Cement Universal Automix (White)
#4214-UK	PANAVIA SA Cement Universal Automix (Translucent)
#4216-UK	PANAVIA SA Cement Universal Automix Trial (Universal(A2))
#4217-UK	PANAVIA SA Cement Universal Automix Trial (Translucent)
#4218-UK	PANAVIA SA Cement Universal Automix Mixing tip
#4221-UK	PANAVIA SA Cement Universal Automix Endo tip (SS)