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	EMERGO EUROPE
European Representative's address	Prinsessegracht 20 2514 AP The Hague, The Netherlands
Name of device	: PANAVIA V5
(Common name, Classification)	UMDNS: Dental Materials, Cement, Resin Composite [16707] GMDN: Dental composite resin kit [62477] 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	: 2021-11

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, ISO 14971: 2019, EN ISO 10993-1:2009, ISO 10993-1:2018, ISO 8601-1:2019, ISO 8601-2:2019, ISO 15223-1:2016, ISO 4049:2009, 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, 2021-09-02

Signature : 山口 聖志

Name : Satoshi Yamaguchi

Title : President

Attachment 1

Type	Product name
#3600-EU	PANAVIA V5 Professional Kit
#3601-EU	PANAVIA V5 Standard Kit (Universal (A2))
#3602-EU	PANAVIA V5 Standard Kit (Clear)
#3604-EU	PANAVIA V5 Introductory Kit (Universal (A2))
#3605-EU	PANAVIA V5 Introductory Kit (Clear)
#3608-EU	PANAVIA V5 Sample Pack (Universal (A2))
#3609-EU	PANAVIA V5 Sample Pack (Clear)
#3611-EU	PANAVIA V5 Paste (Universal (A2))
#3612-EU	PANAVIA V5 Paste (Clear)
#3613-EU	PANAVIA V5 Paste (Brown (A4))
#3614-EU	PANAVIA V5 Paste (White)
#3615-EU	PANAVIA V5 Paste (Opaque)
#3621-EU	PANAVIA V5 Try-in Paste (Universal (A2))
#3622-EU	PANAVIA V5 Try-in Paste (Clear)
#3623-EU	PANAVIA V5 Try-in Paste (Brown (A4))
#3624-EU	PANAVIA V5 Try-in Paste (White)
#3625-EU	PANAVIA V5 Try-in Paste (Opaque)
#3626-EU	PANAVIA V5 Mixing tip
#3629-EU	PANAVIA V5 Endo tip (S)
#3635-EU	PANAVIA V5 Tooth Primer

Type	Product name
#3600-UK	PANAVIA V5 Professional Kit
#3601-UK	PANAVIA V5 Standard Kit (Universal (A2))
#3602-UK	PANAVIA V5 Standard Kit (Clear)
#3604-UK	PANAVIA V5 Introductory Kit (Universal (A2))
#3605-UK	PANAVIA V5 Introductory Kit (Clear)
#3608-UK	PANAVIA V5 Sample Pack (Universal (A2))
#3609-UK	PANAVIA V5 Sample Pack (Clear)
#3611-UK	PANAVIA V5 Paste (Universal (A2))
#3612-UK	PANAVIA V5 Paste (Clear)
#3613-UK	PANAVIA V5 Paste (Brown (A4))
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#3621-UK	PANAVIA V5 Try-in Paste (Universal (A2))

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#3623-UK	PANAVIA V5 Try-in Paste (Brown (A4))
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#3629-UK	PANAVIA V5 Endo tip (S)
#3635-UK	PANAVIA V5 Tooth Primer