

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 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)

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

Place, date : Tokyo, 2021-5-21

Signature : 

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))
#3614-UK	PANAVIA V5 Paste (White)
#3615-UK	PANAVIA V5 Paste (Opaque)
#3621-UK	PANAVIA V5 Try-in Paste (Universal (A2))

#3622-UK	PANAVIA V5 Try-in Paste (Clear)
#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