

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 Veneer LC
 (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 4049:2019, 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 Rheinland LGA Products GmbH
 Tillystraße 2, 90431 Nürnberg, Germany
 (Notified No. 0197)

Place, date : Tokyo, 2022-01-07

Signature : 山口 里 志

Name : Satoshi Yamaguchi

Title : President

Attachment 1

Type	Product name
#4500-EU	PANAVIA Veneer LC Standard Kit (Universal(A2))
#4501-EU	PANAVIA Veneer LC Standard Kit (Clear)
#4503-EU	PANAVIA Veneer LC Trial Kit
#4505-EU	PANAVIA Veneer LC Paste (Universal (A2))
#4506-EU	PANAVIA Veneer LC Paste (Clear)
#4507-EU	PANAVIA Veneer LC Paste (Brown (A4))
#4508-EU	PANAVIA Veneer LC Paste (White)
#4510-EU	PANAVIA Veneer LC Paste Trial (Clear)
#4513-EU	PANAVIA Veneer LC Applicator tip (16G)

Type	Product name
#4500-UK	PANAVIA Veneer LC Standard Kit (Universal(A2))
#4501-UK	PANAVIA Veneer LC Standard Kit (Clear)
#4503-UK	PANAVIA Veneer LC Trial Kit
#4505-UK	PANAVIA Veneer LC Paste (Universal (A2))
#4506-UK	PANAVIA Veneer LC Paste (Clear)
#4507-UK	PANAVIA Veneer LC Paste (Brown (A4))
#4508-UK	PANAVIA Veneer LC Paste (White)
#4510-UK	PANAVIA Veneer LC Paste Trial (Clear)
#4513-UK	PANAVIA Veneer LC Applicator tip (16G)