kuraray

Noritake
Authorized Copy
Michio Takigawa
2015-02-06

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 Resin Composite Cement [16-707]**
	GMDN: Resin-composite dental cement [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	: **2015- 02**

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 780:1997, ISO 7405:2008, EN ISO 14971:2012, EN ISO 10993-1:2009, ISO 8601:2004, EN 980: 2008, ISO 15223-1:2012, EN 62366:2008, ISO 4049:2009**

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,** 2015-01-28

Signature : 有川清之

Name : **Kiyoyuki Arikawa**

Title : **President**

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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)
#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