

## 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 F 2.0  
**(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** : 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)

**Issued by** : TÜV Rheinland LGA Products GmbH  
 : Tillystraße 2, 90431 Nürnberg, Germany  
 (Notified No. 0197)  
 : Tokyo, 2020-09-28

**Place, date**

**Signature** :



**Name** :

Kiyoyuki Arikawa

**Title** :

President



Attachment 1

Type	Product name
# 480 EU	PANAVIA F2.0 Introductory Kit (TC)
# 481 EU	PANAVIA F2.0 Introductory Kit (WHITE)
# 482 EU	PANAVIA F2.0 Introductory Kit (OPAQUE)
# 483 EU	PANAVIA F2.0 Introductory Kit (LIGHT)
# 485 EU	PANAVIA F2.0 Kit (TC)
# 486 EU	PANAVIA F2.0 Kit (WHITE)
# 487 EU	PANAVIA F2.0 Kit (OPAQUE)
# 488 EU	PANAVIA F2.0 Kit (LIGHT)
# 490 EU	PANAVIA F2.0 OXYGUARD II
# 491 EU	PANAVIA F2.0 ED PRIMER II (Liquid A)
# 492 EU	PANAVIA F2.0 ED PRIMER II (Liquid B)
# 493 EU	PANAVIA F2.0 A paste
# 494 EU	PANAVIA F2.0 B paste (TC)
# 495 EU	PANAVIA F2.0 B paste (WHITE)
# 496 EU	PANAVIA F2.0 B paste (OPAQUE)
# 497 EU	PANAVIA F2.0 B paste (LIGHT)

Type	Product name
# 480 UK	PANAVIA F2.0 Introductory Kit (TC)
# 481 UK	PANAVIA F2.0 Introductory Kit (WHITE)
# 482 UK	PANAVIA F2.0 Introductory Kit (OPAQUE)
# 483 UK	PANAVIA F2.0 Introductory Kit (LIGHT)
# 485 UK	PANAVIA F2.0 Kit (TC)
# 486 UK	PANAVIA F2.0 Kit (WHITE)
# 487 UK	PANAVIA F2.0 Kit (OPAQUE)
# 488 UK	PANAVIA F2.0 Kit (LIGHT)
# 490 UK	PANAVIA F2.0 OXYGUARD II
# 491 UK	PANAVIA F2.0 ED PRIMER II (Liquid A)
# 492 UK	PANAVIA F2.0 ED PRIMER II (Liquid B)
# 493 UK	PANAVIA F2.0 A paste
# 494 UK	PANAVIA F2.0 B paste (TC)
# 495 UK	PANAVIA F2.0 B paste (WHITE)
# 496 UK	PANAVIA F2.0 B paste (OPAQUE)
# 497 UK	PANAVIA F2.0 B paste (LIGHT)