

## 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** : CLEARFIL CERAMIC PRIMER PLUS  
 (Common name, Classification) : UMDNS: Dental Materials, Restorative [16188]  
GMDN: Prosthesis priming agent [62474]  
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, 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 里志

**Name** : Satoshi Yamaguchi

**Title** : President

Attachment 1

Type	Product name
# 3637- EU	CLEARFIL CERAMIC PRIMER PLUS
# 3638- EU	CLEARFIL CERAMIC PRIMER PLUS (Trial)

Type	Product name
# 3637- UK	CLEARFIL CERAMIC PRIMER PLUS
# 3638- UK	CLEARFIL CERAMIC PRIMER PLUS (Trial)