kuraray Noritake

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	: **CLEARFIL DC CORE PLUS & Quick KIT**
(Common name, Classification)	**UMDNS: Procedure Kit/Trays, Dental, Restoration, Composite Resin [16734]** **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, 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) 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, 2020-10-19**

Signature : 有川清之

Name : **Kiyoyuki Arikawa**

Title : **President**

Attachment 1

Type	Product name
#3580-EU	CLEARFIL DC CORE PLUS & Quick KIT (Dentin)
#3581-EU	CLEARFIL DC CORE PLUS & Quick KIT (White)

Type	Product name
#3580-UK	CLEARFIL DC CORE PLUS & Quick KIT (Dentin)
#3581-UK	CLEARFIL DC CORE PLUS & Quick KIT (White)