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	: KATANA Cleaner
(Common name, Classification)	UMDNS: Dental Materials, Restorative [16188] GMDN: Dental restoration fixation cleaning solution [62929] Classification: Class IIa (Rule 6)
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, EN 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, 2020-10-19
Signature	: 有川清之
Name	: Kiyoyuki Arikawa
Title	: President

Attachment 1

Type	Product name
#3970-EU	KATANA Cleaner
#3971-EU	KATANA Cleaner(Trial)

Type	Product name
#3970-UK	KATANA Cleaner
#3971-UK	KATANA Cleaner(Trial)