

## 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)

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

**Place, date** : Tokyo, 2020-10-19

**Signature** : 

**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)