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	: **CARIES DETECTOR**
(Common name, Classification)	**UMDNS: Dental Materials, Caries Detection, Dye [20759]** **GMDN: Dental caries detecting stain [60408]** **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, 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, 2020-09-28**

Signature :

Name : **Kiyoyuki Arikawa**

Title : **President**

Attachment 1

Type	Product name
# 220 EU	CARIES DETECTOR

Type	Product name
# 220 UK	CARIES DETECTOR

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Addendum to the original Declaration of Conformity

Name of device: CARIES DETECTOR

Per 01 November 2021, the EU Authorized Representative as listed on the original DoC has changed.

OLD AUTHORIZED REPRESENTATIVE		
Name of company	**Address**	**Telephone/email**
Kuraray Europe GmbH	Philipp-Reis-Str.4, 65795 Hattersheim am Main, Germany	+49.(0)69.305.35835 – phone

NEW AUTHORIZED REPRESENTATIVE		
Name of company	**Address**	**Telephone/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague, The Netherlands	+31.70.345.8570 - phone EmergoEurope@ul.com

DATE: 01/11/2021

UK Type has been unified to EU Type.

OLD ATTACHMENT	
Type	**Product name**
#220-EU	CARIES DETECTOR
Type	**Product name**
#220-UK	CARIES DETECTOR

NEW ATTACHMENT	
Type	**Product name**
#220-EU	CARIES DETECTOR

DATE: 01/11/2022

Per 31 January 2023, the address of our EU Authorized Representative as listed on the original DoC has changed.

OLD ADDRESS AUTHORIZED REPRESENTATIVE		
Name of company	**Address**	**Telephone/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague, The Netherlands	+31.70.345.8570 - phone EmergoEurope@ul.com

NEW ADDRESS AUTHORIZED REPRESENTATIVE		
Name of company	**Address**	**Telephone/email**
Emergo Europe	Westervoortsedijk 60 6827 AT Arnhem, The Netherlands	+31.70.345.8570 - phone EmergoEurope@ul.com

DATE: 31/01/2023

Addition/update of standard

OLD APPLIED STANDARDS
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

NEW APPLIED STANDARDS
EN 1641: 2009, EN ISO 20417: 2021, ISO 780: 2015, ISO 7405: 2018, EN ISO 14971: 2019, EN ISO 10993-1: 2020, ISO 10993-1: 2018, ISO 8601-1: 2019, ISO 8601-2: 2019, EN ISO 15223-1: 2021, EN 62366-1: 2015+AC: 2016, IEC 62366-1: 2015+A1: 2020, EN ISO 13485: 2016+AC: 2018

DATE: 01/02/2024

COMPANY REPRESENTATIVE: Satoshi Yamaguchi

TITLE: President **SIGNATURE:** 山口 聡

DATE: 28/03/2024