

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: Dyes, Dental Caries Detection [20-759]
GMDN: Dental caries detector, optical induced
fluorescence [33995]
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 : 2012- 12

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

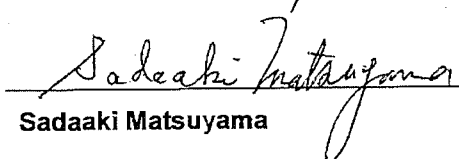
: EN 1641:2009, EN 1041:2008, ISO 780:1997, ISO 7405:2008,
 : EN ISO 14971:2009, EN ISO 10993-1:2009, ISO 8601:2004,
 EN 980:2008, ISO 15223-1:2007, EN 62366: 2008

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, 2012- 11 - 29

Signature : 

Name : Sadaaki Matsuyama

Title : President

Attachment 1

Type	Product name
# 220 EU	CARIES DETECTOR