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	: **ALLOY PRIMER**
(Common name, Classification)	**UMDNS: Dental Porcelain Repair Kits [16-738]**
	GMDN: Prosthesis priming agent [62474]
	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	: **2017-07**

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 7405:2008, EN ISO 14971:2012, EN ISO 10993-1:2009, ISO 8601:2004, EN 980:2008, ISO 15223-1:2016, 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 Reinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg, Germany (Notified No. 0197)**
	:
Place, date	**Tokyo, 2017-06-30**
Signature	: 有川清之
Name	: **Kiyoyuki Arikawa**
Title	: **President**

Authorized Copy

Yasuyuki Ohara

Attachment 1

Type	Product name
# 064 EU	ALLOY PRIMER