

## EC DECLARATION OF CONFORMITY

**Manufacturer:** Kuraray Noritake Dental Inc.  
300 Higashiyama, Miyoshi-cho, Miyoshi, Aichi 470-0293,  
Japan

**European Representative:** Kuraray Europe GmbH  
Philipp-Reis-Str. 4, 65795 Hattersheim, am Main,  
Germany

**Product:** Trade Name: CERABIEN ZR  
CZR PRESS LF  
CZR PRESS  
Description: Dental Porcelain

**Common name:** UMDNS: Dental Porcelains [16-187]  
GMDN: Dental appliance fabrication material, ceramic  
[16187]

**Classification:** Class IIa  
Rule 8 according to Annex IX of the MDD

**Conformity Assessment Route:** Annex II applied (excluding section 4)

We herewith declare that the above-mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer and the notified body.

**General applicable directives:** Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

**Standards:** Harmonized Standards (published in the Official Journal of the European Communities) and applicable standards applicable to this product are:

EN ISO 13485:2016, EN 1641:2009, ISO 9693-2:2016, ISO 6872:2015,  
ISO 7405:2018, EN ISO 10993-1:2009, MEDDEV 2.7/1 Rev.4,  
EN ISO 15223-1:2016, EN 1041:2008, EN ISO 14971:2012

**Notified Body:** SGS Belgium NV  
ID No: 1639

**EC Certificate:** Standard: EN ISO 13485:2016  
Issued by: SGS Belgium NV

**Signature:** 

Date: 2020.9.1

Name Kiyoyuki Arikawa  
Position President

Type	Product name
104-1760EU	CERABIEN ZR SS BASIC FULL KIT (504G)
104-1880EU	CERABIEN ZR SS ESTHETIC WHITE KIT (96G)
104-5490EU	CERABIEN ZR VALUE SHADE FULL KIT (480G)
104-5530EU	CERABIEN ZR TRAIAL KIT SS A2 (23G)
107-0060EU	CZR PRESS TRIAL-H KIT (78G)
107-0130EU	CZR PRESS ESTHETIC WHITE KIT