

EC DECLARATION OF CONFORMITY

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

European Representative: EMERGO EUROPE
Prinsessegracht 20, 2514 AP The Hague,
The Netherlands

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.

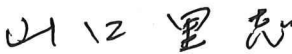
General applicable directives: Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

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: 2021.10.22

Name Satoshi Yamaguchi
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 |
| 104-1760UK | CERABIEN ZR SS BASIC FULL KIT (504G) |
| 104-1880UK | CERABIEN ZR SS ESTHETIC WHITE KIT (96G) |
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