

## 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: 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.

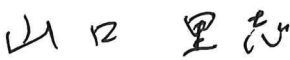
**General applicable directives:** Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

**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
107-0511EU	CZR PRESS L-INGOT LA1 (2GX5)
107-0512EU	CZR PRESS L-INGOT LA1 (5GX5)
107-0521EU	CZR PRESS L-INGOT LA2 (2GX5)
107-0522EU	CZR PRESS L-INGOT LA2 (5GX5)
107-0531EU	CZR PRESS L-INGOT LA3 (2GX5)
107-0532EU	CZR PRESS L-INGOT LA3 (5GX5)
107-0541EU	CZR PRESS L-INGOT LA3.5 (2GX5)
107-0542EU	CZR PRESS L-INGOT LA3.5 (5GX5)
107-0551EU	CZR PRESS L-INGOT LA4 (2GX5)
107-0552EU	CZR PRESS L-INGOT LA4 (5GX5)
107-0561EU	CZR PRESS L-INGOT LB1 (2GX5)
107-0562EU	CZR PRESS L-INGOT LB1 (5GX5)
107-0571EU	CZR PRESS L-INGOT LB2 (2GX5)
107-0572EU	CZR PRESS L-INGOT LB2 (5GX5)
107-0581EU	CZR PRESS L-INGOT LB3 (2GX5)
107-0582EU	CZR PRESS L-INGOT LB3 (5GX5)
107-0591EU	CZR PRESS L-INGOT LB4 (2GX5)
107-0592EU	CZR PRESS L-INGOT LB4 (5GX5)
107-0601EU	CZR PRESS L-INGOT LC1 (2GX5)
107-0602EU	CZR PRESS L-INGOT LC1 (5GX5)
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107-0612EU	CZR PRESS L-INGOT LC2 (5GX5)
107-0621EU	CZR PRESS L-INGOT LC3 (2GX5)
107-0622EU	CZR PRESS L-INGOT LC3 (5GX5)
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107-0632EU	CZR PRESS L-INGOT LC4 (5GX5)
107-0641EU	CZR PRESS L-INGOT LD2 (2GX5)
107-0642EU	CZR PRESS L-INGOT LD2 (5GX5)
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107-0652EU	CZR PRESS L-INGOT LD3 (5GX5)
107-0661EU	CZR PRESS L-INGOT LD4 (2GX5)
107-0662EU	CZR PRESS L-INGOT LD4 (5GX5)
107-0671EU	CZR PRESS L-INGOT LNP1.5 (2GX5)
107-0672EU	CZR PRESS L-INGOT LNP1.5 (5GX5)

107-0681EU	CZR PRESS L-INGOT LNP2.5 (2GX5)
107-0682EU	CZR PRESS L-INGOT LNP2.5 (5GX5)
107-0691EU	CZR PRESS L-INGOT LNW0 (2GX5)
107-0692EU	CZR PRESS L-INGOT LNW0 (5GX5)
107-0701EU	CZR PRESS L-INGOT LNW0.5 (2GX5)
107-0702EU	CZR PRESS L-INGOT LNW0.5 (5GX5)
107-0711EU	CZR PRESS H-INGOT HA1 (2GX5)
107-0712EU	CZR PRESS H-INGOT HA1 (5GX5)
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107-0722EU	CZR PRESS H-INGOT HA2 (5GX5)
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107-0871EU	CZR PRESS H-INGOT HNP1.5 (2GX5)
107-0872EU	CZR PRESS H-INGOT HNP1.5 (5GX5)
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226-2459EU	CZR PRESS PLUNGER (3PCS)
107-0511UK	CZR PRESS L-INGOT LA1 (2GX5)
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107-0782UK	CZR PRESS H-INGOT HB3 (5GX5)
107-0791UK	CZR PRESS H-INGOT HB4 (2GX5)
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107-0881UK	CZR PRESS H-INGOT HNP2.5 (2GX5)
107-0882UK	CZR PRESS H-INGOT HNP2.5 (5GX5)
107-0891UK	CZR PRESS H-INGOT HNW0 (2GX5)
107-0892UK	CZR PRESS H-INGOT HNW0 (5GX5)
107-0901UK	CZR PRESS H-INGOT HNW0.5 (2GX5)
107-0902UK	CZR PRESS H-INGOT HNW0.5 (5GX5)
107-0911UK	CZR PRESS EW-INGOT EW (2GX5)
107-0912UK	CZR PRESS EW-INGOT EW (5GX5)
107-0921UK	CZR PRESS EW-INGOT EW0 (2GX5)
107-0922UK	CZR PRESS EW-INGOT EW0 (5GX5)
107-0931UK	CZR PRESS EW-INGOT EW00 (2GX5)
107-0932UK	CZR PRESS EW-INGOT EW00 (5GX5)
107-0941UK	CZR PRESS EW-INGOT EWY (2GX5)
107-0942UK	CZR PRESS EW-INGOT EWY (5GX5)