

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: CZR PRESS LF
 Description: Dental Porcelain

Common name: UMDNS: Dental Pocerlains [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:

EN1641:2009	Dentistry – Medical devices for dentistry - Materials
ISO6872:2015	Dentistry – Ceramic materials
ISO7405:2008	Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
EN ISO10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk of management process
EN ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
EN 1041:2008	Information supplied by the manufacturer of medical devices

Notified Body: SGS Belgium NV
 ID No: 1639

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

Signature:  Date: 2019.7.28

Name Kiyoyuki Arikawa
 Position President

Type	Product name
107-0010EU	CZR PRESS LF SHADE BASIC STAIN KIT (60G)
107-0020EU	CZR PRESS LF SS MODIFIER KIT (33G)
107-0080EU	CZR PRESS LF ASSOTMENT KIT(160G)
107-0090EU	CZR PRESS LF BASIC KIT (190G)
107-0100EU	CZR PRESS LF EXTERNAL STAIN KIT (73G)
107-0120EU	CZR PRESS LF IS COMPLETE KIT (57G)
107-0140EU	CZR PRESS LF EW LAYERING KIT (89G)
107-0150EU	CZR PRESS LF LUSTER CCV KIT (160G)
107-0160EU	CZR PRESS LF TISSUE KIT (70G)
107-0951EU	CZR PRESS LF BODY EW0B (10G)
107-0952EU	CZR PRESS LF BODY EW0B (50G)
107-0953EU	CZR PRESS LF BODY EW0B (200G)
107-0961EU	CZR PRESS LF BODY EWB (10G)
107-0962EU	CZR PRESS LF BODY EWB (50G)
107-0963EU	CZR PRESS LF BODY EWB (200G)
107-0971EU	CZR PRESS LF BODY EWYB (10G)
107-0972EU	CZR PRESS LF BODY EWYB (50G)
107-0973EU	CZR PRESS LF BODY EWYB (200G)
107-0981EU	CZR PRESS LF BODY HA1B (10G)
107-0982EU	CZR PRESS LF BODY HA1B (50G)
107-0983EU	CZR PRESS LF BODY HA1B (200G)
107-0991EU	CZR PRESS LF BODY HA3B (10G)
107-0992EU	CZR PRESS LF BODY HA3B (50G)
107-0993EU	CZR PRESS LF BODY HA3B (200G)
107-1001EU	CZR PRESS LF BODY HA4B (10G)
107-1002EU	CZR PRESS LF BODY HA4B (50G)
107-1003EU	CZR PRESS LF BODY HA4B (200G)
107-1011EU	CZR PRESS LF BODY HB2B (10G)
107-1012EU	CZR PRESS LF BODY HB2B (50G)
107-1013EU	CZR PRESS LF BODY HB2B (200G)
107-1021EU	CZR PRESS LF BODY HC2B (10G)
107-1022EU	CZR PRESS LF BODY HC2B (50G)
107-1023EU	CZR PRESS LF BODY HC2B (200G)
107-1031EU	CZR PRESS LF BODY HD2B (10G)

107-1032EU	CZR PRESS LF BODY HD2B (50G)
107-1033EU	CZR PRESS LF BODY HD2B (200G)
107-1041EU	CZR PRESS LF BODY HNW0B (10G)
107-1042EU	CZR PRESS LF BODY HNW0B (50G)
107-1043EU	CZR PRESS LF BODY HNW0B (200G)
107-1051EU	CZR PRESS LF ENAMEL E1 (10G)
107-1052EU	CZR PRESS LF ENAMEL E1 (50G)
107-1053EU	CZR PRESS LF ENAMEL E1 (200G)
107-1061EU	CZR PRESS LF ENAMEL E2 (10G)
107-1062EU	CZR PRESS LF ENAMEL E2 (50G)
107-1063EU	CZR PRESS LF ENAMEL E2 (200G)
107-1071EU	CZR PRESS LF ENAMEL E3 (10G)
107-1072EU	CZR PRESS LF ENAMEL E3 (50G)
107-1073EU	CZR PRESS LF ENAMEL E3 (200G)
107-1081EU	CZR PRESS LF ENAMEL SILKY E1 (10G)
107-1082EU	CZR PRESS LF ENAMEL SILKY E1 (50G)
107-1083EU	CZR PRESS LF ENAMEL SILKY E1 (200G)
107-1091EU	CZR PRESS LF ENAMEL SILKY E2 (10G)
107-1092EU	CZR PRESS LF ENAMEL SILKY E2 (50G)
107-1093EU	CZR PRESS LF ENAMEL SILKY E2 (200G)
107-1101EU	CZR PRESS LF TRANSLUCENT TX (10G)
107-1102EU	CZR PRESS LF TRANSLUCENT TX (50G)
107-1103EU	CZR PRESS LF TRANSLUCENT TX (200G)
107-1111EU	CZR PRESS LF TRANSLUCENT T0 (10G)
107-1112EU	CZR PRESS LF TRANSLUCENT T0 (50G)
107-1113EU	CZR PRESS LF TRANSLUCENT T0 (200G)
107-1121EU	CZR PRESS LF TRANSLUCENT T1 (10G)
107-1122EU	CZR PRESS LF TRANSLUCENT T1 (50G)
107-1123EU	CZR PRESS LF TRANSLUCENT T1 (200G)
107-1131EU	CZR PRESS LF TRANSLUCENT T2 (10G)
107-1132EU	CZR PRESS LF TRANSLUCENT T2 (50G)
107-1133EU	CZR PRESS LF TRANSLUCENT T2 (200G)
107-1141EU	CZR PRESS LF LUSTER LT0 (10G)
107-1142EU	CZR PRESS LF LUSTER LT0 (50G)
107-1143EU	CZR PRESS LF LUSTER LT0 (200G)

107-1151EU	CZR PRESS LF LUSTER LT1 (10G)
107-1152EU	CZR PRESS LF LUSTER LT1 (50G)
107-1153EU	CZR PRESS LF LUSTER LT1 (200G)
107-1161EU	CZR PRESS LF LUSTER T-BLUE (10G)
107-1162EU	CZR PRESS LF LUSTER T-BLUE (50G)
107-1163EU	CZR PRESS LF LUSTER T-BLUE (200G)
107-1171EU	CZR PRESS LF LUSTER AQUA BLUE 1 (10G)
107-1172EU	CZR PRESS LF LUSTER AQUA BLUE 1 (50G)
107-1173EU	CZR PRESS LF LUSTER AQUA BLUE 1 (200G)
107-1181EU	CZR PRESS LF LUSTER AQUA BLUE 2 (10G)
107-1182EU	CZR PRESS LF LUSTER AQUA BLUE 2 (50G)
107-1183EU	CZR PRESS LF LUSTER AQUA BLUE 2 (200G)
107-1191EU	CZR PRESS LF LUSTER LT-NATURAL (10G)
107-1192EU	CZR PRESS LF LUSTER LT-NATURAL (50G)
107-1193EU	CZR PRESS LF LUSTER LT-NATURAL (200G)
107-1201EU	CZR PRESS LF LUSTER LT SUPER GRAY (10G)
107-1202EU	CZR PRESS LF LUSTER LT SUPER GRAY (50G)
107-1203EU	CZR PRESS LF LUSTER LT SUPER GRAY (200G)
107-1211EU	CZR PRESS LF LUSTER LT YELLOW (10G)
107-1212EU	CZR PRESS LF LUSTER LT YELLOW (50G)
107-1213EU	CZR PRESS LF LUSTER LT YELLOW (200G)
107-1221EU	CZR PRESS LF LUSTER INCISAL AUREOLA (10G)
107-1222EU	CZR PRESS LF LUSTER INCISAL AUREOLA (50G)
107-1223EU	CZR PRESS LF LUSTER INCISAL AUREOLA (200G)
107-1231EU	CZR PRESS LF LUSTER SUN BRIGHT (10G)
107-1232EU	CZR PRESS LF LUSTER SUN BRIGHT (50G)
107-1233EU	CZR PRESS LF LUSTER SUN BRIGHT (200G)
107-1241EU	CZR PRESS LF LUSTER CREAMY ENAMEL (10G)
107-1242EU	CZR PRESS LF LUSTER CREAMY ENAMEL (50G)
107-1243EU	CZR PRESS LF LUSTER CREAMY ENAMEL (200G)
107-1251EU	CZR PRESS LF LUSTER CREAMY WHITE (10G)
107-1252EU	CZR PRESS LF LUSTER CREAMY WHITE (50G)
107-1253EU	CZR PRESS LF LUSTER CREAMY WHITE (200G)
107-1261EU	CZR PRESS LF LUSTER ELT 1 (10G)
107-1262EU	CZR PRESS LF LUSTER ELT 1 (50G)

107-1263EU	CZR PRESS LF LUSTER ELT 1 (200G)
107-1271EU	CZR PRESS LF LUSTER ELT 2 (10G)
107-1272EU	CZR PRESS LF LUSTER ELT 2 (50G)
107-1273EU	CZR PRESS LF LUSTER ELT 2 (200G)
107-1281EU	CZR PRESS LF LUSTER ELT 3 (10G)
107-1282EU	CZR PRESS LF LUSTER ELT 3 (50G)
107-1283EU	CZR PRESS LF LUSTER ELT 3 (200G)
107-1291EU	CZR PRESS LF CLEAR CERVICAL CCV-1 (10G)
107-1292EU	CZR PRESS LF CLEAR CERVICAL CCV-1 (50G)
107-1293EU	CZR PRESS LF CLEAR CERVICAL CCV-1 (200G)
107-1301EU	CZR PRESS LF CLEAR CERVICAL CCV-2 (10G)
107-1302EU	CZR PRESS LF CLEAR CERVICAL CCV-2 (50G)
107-1303EU	CZR PRESS LF CLEAR CERVICAL CCV-2 (200G)
107-1311EU	CZR PRESS LF CLEAR CERVICAL CCV-3 (10G)
107-1312EU	CZR PRESS LF CLEAR CERVICAL CCV-3 (50G)
107-1313EU	CZR PRESS LF CLEAR CERVICAL CCV-3 (200G)
107-1321EU	CZR PRESS LF CLEAR CERVICAL CCV-4 (10G)
107-1322EU	CZR PRESS LF CLEAR CERVICAL CCV-4 (50G)
107-1323EU	CZR PRESS LF CLEAR CERVICAL CCV-4 (200G)
107-1331EU	CZR PRESS LF MAMELON 1 (10G)
107-1332EU	CZR PRESS LF MAMELON 1 (50G)
107-1341EU	CZR PRESS LF MAMELON 2 (10G)
107-1342EU	CZR PRESS LF MAMELON 2 (50G)
107-1351EU	CZR PRESS LF TISSUE 1 (10G)
107-1352EU	CZR PRESS LF TISSUE 1 (50G)
107-1361EU	CZR PRESS LF TISSUE 2 (10G)
107-1362EU	CZR PRESS LF TISSUE 2 (50G)
107-1371EU	CZR PRESS LF TISSUE 3 (10G)
107-1372EU	CZR PRESS LF TISSUE 3 (50G)
107-1381EU	CZR PRESS LF TISSUE 4 (10G)
107-1382EU	CZR PRESS LF TISSUE 4 (50G)
107-1391EU	CZR PRESS LF TISSUE 5 (10G)
107-1392EU	CZR PRESS LF TISSUE 5 (50G)
107-1401EU	CZR PRESS LF TISSUE 6 (10G)
107-1402EU	CZR PRESS LF TISSUE 6 (50G)

107-1411EU	CZR PRESS LF TISSUE 7 (10G)
107-1412EU	CZR PRESS LF TISSUE 7 (50G)
107-1421EU	CZR PRESS LF ADD-ON BODY AD-B (10G)
107-1422EU	CZR PRESS LF ADD-ON BODY AD-B (50G)
107-1431EU	CZR PRESS LF ADD-ON TRANS. AD-T (10G)
107-1432EU	CZR PRESS LF ADD-ON TRANS. AD-T (50G)
107-1441EU	CZR PRESS LF ES GRAY (3G)
107-1451EU	CZR PRESS LF ES PURE WHITE (3G)
107-1461EU	CZR PRESS LF ES BLACK (3G)
107-1471EU	CZR PRESS LF ES BLUE (3G)
107-1481EU	CZR PRESS LF ES GREEN 1 (3G)
107-1491EU	CZR PRESS LF ES GREEN 2 (3G)
107-1501EU	CZR PRESS LF ES ORANGE 1 (3G)
107-1511EU	CZR PRESS LF ES ORANGE 2 (3G)
107-1521EU	CZR PRESS LF ES YELLOW (3G)
107-1531EU	CZR PRESS LF ES CERVICAL 1 (3G)
107-1541EU	CZR PRESS LF ES CERVICAL 2 (3G)
107-1551EU	CZR PRESS LF ES CERVICAL 3 (3G)
107-1561EU	CZR PRESS LF ES EARTH BROWN (3G)
107-1571EU	CZR PRESS LF ES REDDISH BROWN (3G)
107-1581EU	CZR PRESS LF ES SALMON PINK (3G)
107-1591EU	CZR PRESS LF ES PINK (3G)
107-1601EU	CZR PRESS LF ES RED (3G)
107-1611EU	CZR PRESS LF ES A+ (3G)
107-1621EU	CZR PRESS LF ES B+ (3G)
107-1631EU	CZR PRESS LF ES C+ (3G)
107-1641EU	CZR PRESS LF ES D+ (3G)
107-1651EU	CZR PRESS LF ES GLAZE (10G)
107-1661EU	CZR PRESS LF IS WHITE (3G)
107-1671EU	CZR PRESS LF IS GRAY (3G)
107-1681EU	CZR PRESS LF IS INCISAL BLUE 1(3G)
107-1691EU	CZR PRESS LF IS INCISAL BLUE 2(3G)
107-1701EU	CZR PRESS LF IS MAMELON ORANGE 1 (3G)
107-1711EU	CZR PRESS LF IS MAMELON ORANGE 2 (3G)
107-1721EU	CZR PRESS LF IS CERVICAL 1 (3G)

107-1731EU	CZR PRESS LF IS CERVICAL 2 (3G)
107-1741EU	CZR PRESS LF IS CERVICAL 3 (3G)
107-1751EU	CZR PRESS LF IS EARTH BROWN (3G)
107-1761EU	CZR PRESS LF IS REDDISH BROWN (3G)
107-1771EU	CZR PRESS LF IS RED (3G)
107-1781EU	CZR PRESS LF IS SALMON PINK (3G)
107-1791EU	CZR PRESS LF IS A+ (3G)
107-1801EU	CZR PRESS LF IS B+ (3G)
107-1811EU	CZR PRESS LF IS C+ (3G)
107-1821EU	CZR PRESS LF IS D+ (3G)
107-1831EU	CZR PRESS LF IS FLUORO (3G)
107-1841EU	CZR PRESS LF IS BRIGHTT (DILUTION) (3G)
107-1851EU	CZR PRESS LF MARGIN MRP (10G)
107-0191EU	CZR PRESS LF SB-STAIN SSA1 (3G)
107-0201EU	CZR PRESS LF SB-STAIN SSA2 (3G)
107-0211EU	CZR PRESS LF SB-STAIN SSA3 (3G)
107-0221EU	CZR PRESS LF SB-STAIN SSA3.5 (3G)
107-0231EU	CZR PRESS LF SB-STAIN SSA4 (3G)
107-0241 EU	CZR PRESS LF SB-STAIN SSB1 (3G)
107-0251 EU	CZR PRESS LF SB-STAIN SSB2 (3G)
107-0261 EU	CZR PRESS LF SB-STAIN SSB3 (3G)
107-0271 EU	CZR PRESS LF SB-STAIN SSB4 (3G)
107-0281 EU	CZR PRESS LF SB-STAIN SSC1 (3G)
107-0291 EU	CZR PRESS LF SB-STAIN SSC2 (3G)
107-0301 EU	CZR PRESS LF SB-STAIN SSC3 (3G)
107-0311 EU	CZR PRESS LF SB-STAIN SSC4 (3G)
107-0321 EU	CZR PRESS LF SB-STAIN SSD2 (3G)
107-0331 EU	CZR PRESS LF SB-STAIN SSD3 (3G)
107-0341 EU	CZR PRESS LF SB-STAIN SSD4 (3G)
107-0351 EU	CZR PRESS LF SB-STAIN SSNP1.5 (3G)
107-0361 EU	CZR PRESS LF SB-STAIN SSNP2.5 (3G)
107-0371 EU	CZR PRESS LF SB-STAIN SSNM0 (3G)
107-0381 EU	CZR PRESS LF SB-STAIN SSNM0.5 (3G)
107-0391 EU	CZR PRESS LF SB-STAIN WHITE (3G)
107-0401 EU	CZR PRESS LF SB-STAIN MOD.GRAY (3G)

107-0411 EU	CZR PRESS LF SB-STAIN MOD.INC.BLUE1 (3G)
107-0421 EU	CZR PRESS LF SB-STAIN MOD.INC.BLUE2 (3G)
107-0431 EU	CZR PRESS LF SB-STAIN MOD.CV ORANGE (3G)
107-0441 EU	CZR PRESS LF SB-STAIN MOD. EARTH BROWN (3G)
107-0451 EU	CZR PRESS LF SB-STAIN MOD. SALMON PINK (3G)
107-0461 EU	CZR PRESS LF SB-STAIN MOD. A+ (3G)
107-0471 EU	CZR PRESS LF SB-STAIN MOD. B+ (3G)
107-0481 EU	CZR PRESS LF SB-STAIN MOD. C+ (3G)
107-0491 EU	CZR PRESS LF SB-STAIN MOD. D+ (3G)
107-0501 EU	CZR PRESS LF SB-STAIN MOD. FLUORO (3G)
126-0091EU	ES LIQID(10ML)
126-0102EU	ES LIQID(100ML)
126-0111EU	IS LIQID(10ML)
126-0122EU	IS LIQID(100ML)
126-0232EU	LF LIQID(100ML)
211-0769EU	ES COROL GUIDE
211-0779EU	IS COROL GUIDE