

## 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: KATANA Zirconia  
Description: Dental Ceramic Block

**Common name:** UMDNS: Prostheses, Dental Fixed, Crown, Total [23-616]  
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 9693:2019, 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+A1:2013, EN ISO 14971:2012

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

**EC Certificate:** Standard: EN ISO13485:2016  
Issued by: SGS Belgium NV

**Signature:**  Date: 2020/11/20

Name Kiyoyuki Arikawa  
Position President

Type	Product name
125-2111EU	KATANA ZR HT10 Straight / T:10MM
125-2122EU	KATANA ZR HT10 Collar / T:14MM
125-2133EU	KATANA ZR HT10 Collar / T:18MM
125-2144EU	KATANA ZR HT10 Collar / T:22MM
125-2155EU	KATANA ZR HT10 Collar / T:26MM
125-7387EU	KATANA ZR HT10 Collar / T:30MM
125-2251EU	KATANA ZR HT12 Straight / T:10MM
125-2262EU	KATANA ZR HT12 Collar / T:14MM
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125-2284EU	KATANA ZR HT12 Collar/ T:22MM
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125-3144UK	KATANA ZR STML A1 COLLAR / T:22MM
125-3152UK	KATANA ZR STML A2 COLLAR / T:14MM
125-3163UK	KATANA ZR STML A2 COLLAR / T:18MM
125-3174UK	KATANA ZR STML A2 COLLAR / T:22MM
125-3182UK	KATANA ZR STML A3 COLLAR / T:14MM
125-3193UK	KATANA ZR STML A3 COLLAR / T:18MM
125-3204UK	KATANA ZR STML A3 COLLAR / T:22MM
125-3212UK	KATANA ZR STML A3.5 COLLAR / T:14MM
125-3223UK	KATANA ZR STML A3.5 COLLAR / T:18MM
125-3234UK	KATANA ZR STML A3.5 COLLAR / T:22MM
125-5232UK	KATANA ZR STML A4 COLLAR / T:14MM
125-5243UK	KATANA ZR STML A4 COLLAR / T:18MM
125-5254UK	KATANA ZR STML A4 COLLAR / T:22MM
125-5262UK	KATANA ZR STML B1 COLLAR / T:14MM
125-5273UK	KATANA ZR STML B1 COLLAR / T:18MM
125-5284UK	KATANA ZR STML B1 COLLAR / T:22MM
125-5303UK	KATANA ZR STML B2 COLLAR / T:14MM
125-5314UK	KATANA ZR STML B2 COLLAR / T:18MM
125-5322UK	KATANA ZR STML B2 COLLAR / T:22MM
125-5333UK	KATANA ZR STML B3 COLLAR / T:14MM
125-5344UK	KATANA ZR STML B3 COLLAR / T:18MM
125-5352UK	KATANA ZR STML B3 COLLAR / T:22MM
125-5352UK	KATANA ZR STML C1 COLLAR / T:14MM
125-5363UK	KATANA ZR STML C1 COLLAR / T:18MM
125-5374UK	KATANA ZR STML C1 COLLAR / T:22MM
125-5382UK	KATANA ZR STML C2 COLLAR / T:14MM
125-5393UK	KATANA ZR STML C2 COLLAR / T:18MM

125-5404UK	KATANA ZR STML C2 COLLAR / T:22MM
125-5412UK	KATANA ZR STML C3 COLLAR / T:14MM
125-5423UK	KATANA ZR STML C3 COLLAR / T:18MM
125-5434UK	KATANA ZR STML C3 COLLAR / T:22MM
125-5442UK	KATANA ZR STML D2 COLLAR / T:14MM
125-5453UK	KATANA ZR STML D2 COLLAR / T:18MM
125-5464UK	KATANA ZR STML D2 COLLAR / T:22MM
125-5472UK	KATANA ZR STML D3 COLLAR / T:14MM
125-5483UK	KATANA ZR STML D3 COLLAR / T:18MM
125-5494UK	KATANA ZR STML D3 COLLAR / T:22MM
125-3242UK	KATANA ZR STML NW COLLAR / T:14MM
125-3253UK	KATANA ZR STML NW COLLAR / T:18MM
125-3264UK	KATANA ZR STML NW COLLAR / T:22MM
125-3272UK	KATANA ZR UT10 / T:14MM
125-3283UK	KATANA ZR UT10 / T:18MM
125-3302UK	KATANA ZR UTML EA1 COLLAR / T:14MM
125-3313UK	KATANA ZR UTML EA1 COLLAR / T:18MM
125-3332UK	KATANA ZR UTML EA2 COLLAR / T:14MM
125-3343UK	KATANA ZR UTML EA2 COLLAR / T:18MM
125-3362UK	KATANA ZR UTML EA3 COLLAR / T:14MM
125-3373UK	KATANA ZR UTML EA3 COLLAR / T:18MM
125-3392UK	KATANA ZR UTML ENW COLLAR / T:14MM
125-3403UK	KATANA ZR UTML ENW COLLAR / T:18MM
125-3842UK	KATANA ZR UTML A1 COLLAR / T:14MM
125-3853UK	KATANA ZR UTML A1 COLLAR / T:18MM
125-3872UK	KATANA ZR UTML A2 COLLAR / T:14MM
125-3883UK	KATANA ZR UTML A2 COLLAR / T:18MM
125-3902UK	KATANA ZR UTML A3 COLLAR / T:14MM
125-3913UK	KATANA ZR UTML A3 COLLAR / T:18MM
125-3932UK	KATANA ZR UTML A3.5 COLLAR / T:14MM
125-3943UK	KATANA ZR UTML A3.5 COLLAR / T:18MM
125-3962UK	KATANA ZR UTML A4 COLLAR / T:14MM
125-3973UK	KATANA ZR UTML A4 COLLAR / T:18MM
125-3992UK	KATANA ZR UTML B1 COLLAR / T:14MM
125-4003UK	KATANA ZR UTML B1 COLLAR / T:18MM
125-4022UK	KATANA ZR UTML B2 COLLAR / T:14MM
125-4033UK	KATANA ZR UTML B2 COLLAR / T:18MM

125-4052UK	KATANA ZR UTML B3 COLLAR / T:14MM
125-4063UK	KATANA ZR UTML B3 COLLAR / T:18MM
125-4082UK	KATANA ZR UTML B4 COLLAR / T:14MM
125-4093UK	KATANA ZR UTML B4 COLLAR / T:18MM
125-4112UK	KATANA ZR UTML C1 COLLAR / T:14MM
125-4123UK	KATANA ZR UTML C1 COLLAR / T:18MM
125-4142UK	KATANA ZR UTML C2 COLLAR / T:14MM
125-4153UK	KATANA ZR UTML C2 COLLAR / T:18MM
125-4172UK	KATANA ZR UTML C3 COLLAR / T:14MM
125-4183UK	KATANA ZR UTML C3 COLLAR / T:18MM
125-4202UK	KATANA ZR UTML C4 COLLAR / T:14MM
125-4213UK	KATANA ZR UTML C4 COLLAR / T:18MM
125-4232UK	KATANA ZR UTML D2 COLLAR / T:14MM
125-4243UK	KATANA ZR UTML D2 COLLAR / T:18MM
125-4262UK	KATANA ZR UTML D3 COLLAR / T:14MM
125-4273UK	KATANA ZR UTML D3 COLLAR / T:18MM
125-4292UK	KATANA ZR UTML D4 COLLAR / T:14MM
125-4303UK	KATANA ZR UTML D4 COLLAR / T:18MM
125-6441UK	KATANA ZR LT10 Straight / T:10MM
125-6452UK	KATANA ZR LT10 Collar / T:14MM
125-6463UK	KATANA ZR LT10 Collar / T:18MM
125-6474UK	KATANA ZR LT10 Collar / T:22MM
125-6485UK	KATANA ZR LT10 Collar / T:26MM
125-6491UK	KATANA ZR LT12 Straight / T:10MM
125-6502UK	KATANA ZR LT12 Collar / T:14MM
125-6513UK	KATANA ZR LT12 Collar / T:18MM
125-6524UK	KATANA ZR LT12 Collar/ T:22MM
125-6535UK	KATANA ZR LT12 Collar / T:26MM
125-6541UK	KATANA ZR LT13 Straight / T:10MM
125-6552UK	KATANA ZR LT13 Collar / T:14MM
125-6563UK	KATANA ZR LT13 Collar / T:18MM
125-6574UK	KATANA ZR LT13 Collar / T:22MM
125-6585UK	KATANA ZR LT13 Collar / T:26MM

125-7932UK	KATANA ZR YML A1 COLLAR / T:14MM
125-7943UK	KATANA ZR YML A1 COLLAR / T:18MM
125-7954UK	KATANA ZR YML A1 COLLAR / T:22MM
125-7962UK	KATANA ZR YML A2 COLLAR / T:14MM
125-7973UK	KATANA ZR YML A2 COLLAR / T:18MM
125-7984UK	KATANA ZR YML A2 COLLAR / T:22MM
125-7992UK	KATANA ZR YML A3 COLLAR / T:14MM
125-8003UK	KATANA ZR YML A3 COLLAR / T:18MM
125-8014UK	KATANA ZR YML A3 COLLAR / T:22MM
125-8022UK	KATANA ZR YML A3.5 COLLAR / T:14MM
125-8033UK	KATANA ZR YML A3.5 COLLAR / T:18MM
125-8044UK	KATANA ZR YML A3.5 COLLAR / T:22MM
125-8052UK	KATANA ZR YML A4 COLLAR / T:14MM
125-8063UK	KATANA ZR YML A4 COLLAR / T:18MM
125-8074UK	KATANA ZR YML A4 COLLAR / T:22MM
125-8082UK	KATANA ZR YML B1 COLLAR / T:14MM
125-8093UK	KATANA ZR YML B1 COLLAR / T:18MM
125-8104UK	KATANA ZR YML B1 COLLAR / T:22MM
125-8112UK	KATANA ZR YML B2 COLLAR / T:14MM
125-8123UK	KATANA ZR YML B2 COLLAR / T:18MM
125-8134UK	KATANA ZR YML B2 COLLAR / T:22MM
125-8142UK	KATANA ZR YML B3 COLLAR / T:14MM
125-8153UK	KATANA ZR YML B3 COLLAR / T:18MM
125-8164UK	KATANA ZR YML B3 COLLAR / T:22MM
125-8172UK	KATANA ZR YML C1 COLLAR / T:14MM
125-8183UK	KATANA ZR YML C1 COLLAR / T:18MM
125-8194UK	KATANA ZR YML C1 COLLAR / T:22MM
125-8202UK	KATANA ZR YML C2 COLLAR / T:14MM
125-8213UK	KATANA ZR YML C2 COLLAR / T:18MM
125-8224UK	KATANA ZR YML C2 COLLAR / T:22MM
125-8232UK	KATANA ZR YML C3 COLLAR / T:14MM
125-8243UK	KATANA ZR YML C3 COLLAR / T:18MM
125-8254UK	KATANA ZR YML C3 COLLAR / T:22MM
125-8262UK	KATANA ZR YML D2 COLLAR / T:14MM
125-8273UK	KATANA ZR YML D2 COLLAR / T:18MM
125-8284UK	KATANA ZR YML D2 COLLAR / T:22MM
125-8292UK	KATANA ZR YML D3 COLLAR / T:14MM

125-8303UK	KATANA ZR YML D3 COLLAR / T:18MM
125-8314UK	KATANA ZR YML D3 COLLAR / T:22MM
125-8322UK	KATANA ZR YML NW COLLAR / T:14MM
125-8333UK	KATANA ZR YML NW COLLAR / T:18MM
125-8344UK	KATANA ZR YML NW COLLAR / T:22MM
125-8772UK	KATANA ZR YML NA1 COLLAR / T:14MM
125-8783UK	KATANA ZR YML NA1 COLLAR / T:18MM
125-8794UK	KATANA ZR YML NA1 COLLAR / T:22MM
125-8802UK	KATANA ZR YML NA2 COLLAR / T:14MM
125-8813UK	KATANA ZR YML NA2 COLLAR / T:18MM
125-8824UK	KATANA ZR YML NA2 COLLAR / T:22MM
125-8832UK	KATANA ZR YML NA3 COLLAR / T:14MM
125-8843UK	KATANA ZR YML NA3 COLLAR / T:18MM
125-8854UK	KATANA ZR YML NA3 COLLAR / T:22MM
125-8862UK	KATANA ZR YML NA3.5 COLLAR / T:14MM
125-8873UK	KATANA ZR YML NA3.5 COLLAR / T:18MM
125-8884UK	KATANA ZR YML NA3.5 COLLAR / T:22MM
125-8892UK	KATANA ZR YML NA4 COLLAR / T:14MM
125-8903UK	KATANA ZR YML NA4 COLLAR / T:18MM
125-8914UK	KATANA ZR YML NA4 COLLAR / T:22MM