

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: 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.

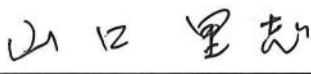
General applicable directives: Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

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: 
Name Yamaguchi Satoshi
Position President

Date: 2021.10.25

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
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127-0065EU	Esthetic Colorant B plus 12ml
127-0075EU	Esthetic Colorant C plus 12ml
127-0085EU	Esthetic Colorant D plus 12ml
127-0095EU	Esthetic Colorant BROWN 12ml
127-0105EU	Esthetic Colorant ORANGE 12ml
127-0115EU	Esthetic Colorant GRAY 12ml
127-0125EU	Esthetic Colorant BLUE 12ml
127-0135EU	Esthetic Colorant VIOLET 12ml
127-0145EU	Esthetic Colorant PINK 12ml
127-0155EU	Esthetic Colorant WHITE 12ml
127-0165EU	Esthetic Colorant OPAQUE 12ml

127-0010EU	Esthetic Colorant Basic Kit
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125-2111UK	KATANA ZR HT10 Straight / T:10MM
125-2122UK	KATANA ZR HT10 Collar / T:14MM
125-2133UK	KATANA ZR HT10 Collar / T:18MM
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125-2244UK	KATANA ZR ML B Light Collar / T:22MM
125-2642UK	KATANA ZR ML C LIGHT COLLAR / T:14MM
125-2653UK	KATANA ZR ML C LIGHT COLLAR / T:18MM
125-2664UK	KATANA ZR ML C LIGHT COLLAR / T:22MM
125-2672UK	KATANA ZR ML D LIGHT COLLAR / T:14MM
125-2683UK	KATANA ZR ML D LIGHT COLLAR / T:18MM
125-2694UK	KATANA ZR ML D LIGHT COLLAR / T:22MM
125-2702UK	KATANA ZR ML A WHITE COLLAR / T:14MM
125-2713UK	KATANA ZR ML A WHITE COLLAR / T:18MM
125-2724UK	KATANA ZR ML A WHITE COLLAR / T:22MM

125-6942UK	KATANA ZR HTML A1 COLLAR / T:14MM
125-6953UK	KATANA ZR HTML A1 COLLAR / T:18MM
125-6964UK	KATANA ZR HTML A1 COLLAR / T:22MM
125-6972UK	KATANA ZR HTML A2 COLLAR / T:14MM
125-6983UK	KATANA ZR HTML A2 COLLAR / T:18MM
125-6994UK	KATANA ZR HTML A2 COLLAR / T:22MM
125-7002UK	KATANA ZR HTML A3 COLLAR / T:14MM
125-7013UK	KATANA ZR HTML A3 COLLAR / T:18MM
125-7024UK	KATANA ZR HTML A3 COLLAR / T:22MM
125-7032UK	KATANA ZR HTML A3.5 COLLAR / T:14MM
125-7043UK	KATANA ZR HTML A3.5 COLLAR / T:18MM
125-7054UK	KATANA ZR HTML A3.5 COLLAR / T:22MM
125-7062UK	KATANA ZR HTML A4 COLLAR / T:14MM
125-7073UK	KATANA ZR HTML A4 COLLAR / T:18MM
125-7084UK	KATANA ZR HTML A4 COLLAR / T:22MM
125-7092UK	KATANA ZR HTML B1 COLLAR / T:14MM
125-7103UK	KATANA ZR HTML B1 COLLAR / T:18MM
125-7114UK	KATANA ZR HTML B1 COLLAR / T:22MM
125-7122UK	KATANA ZR HTML B2 COLLAR / T:14MM
125-7133UK	KATANA ZR HTML B2 COLLAR / T:18MM
125-7144UK	KATANA ZR HTML B2 COLLAR / T:22MM
125-7152UK	KATANA ZR HTML B3 COLLAR / T:14MM
125-7163UK	KATANA ZR HTML B3 COLLAR / T:18MM
125-7174UK	KATANA ZR HTML B3 COLLAR / T:22MM
125-7182UK	KATANA ZR HTML C1 COLLAR / T:14MM
125-7193UK	KATANA ZR HTML C1 COLLAR / T:18MM
125-7204UK	KATANA ZR HTML C1 COLLAR / T:22MM
125-7212UK	KATANA ZR HTML C2 COLLAR / T:14MM
125-7223UK	KATANA ZR HTML C2 COLLAR / T:18MM
125-7234UK	KATANA ZR HTML C2 COLLAR / T:22MM
125-7242UK	KATANA ZR HTML C3 COLLAR / T:14MM
125-7253UK	KATANA ZR HTML C3 COLLAR / T:18MM
125-7264UK	KATANA ZR HTML C3 COLLAR / T:22MM
125-7272UK	KATANA ZR HTML D2 COLLAR / T:14MM
125-7283UK	KATANA ZR HTML D2 COLLAR / T:18MM
125-7294UK	KATANA ZR HTML D2 COLLAR / T:22MM
125-7302UK	KATANA ZR HTML D3 COLLAR / T:14MM

125-7313UK	KATANA ZR HTML D3 COLLAR / T:18MM
125-7324UK	KATANA ZR HTML D3 COLLAR / T:22MM
125-6912UK	KATANA ZR HTML NW COLLAR / T:14MM
125-6923UK	KATANA ZR HTML NW COLLAR / T:18MM
125-6934UK	KATANA ZR HTML NW COLLAR / T:22MM
125-3092UK	KATANA ZR ST10 / T:14MM
125-3103UK	KATANA ZR ST10 / T:18MM
125-3114UK	KATANA ZR ST10 / T:22MM
125-3122UK	KATANA ZR STML A1 COLLAR / T:14MM
125-3133UK	KATANA ZR STML A1 COLLAR / T:18MM
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
125-5292UK	KATANA ZR STML B2 COLLAR / T:14MM
125-5303UK	KATANA ZR STML B2 COLLAR / T:18MM
125-5314UK	KATANA ZR STML B2 COLLAR / T:22MM
125-5322UK	KATANA ZR STML B3 COLLAR / T:14MM
125-5333UK	KATANA ZR STML B3 COLLAR / T:18MM
125-5344UK	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
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125-8224UK	KATANA ZR YML C2 COLLAR / T:22MM
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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
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125-8813UK	KATANA ZR YML NA2 COLLAR / T:18MM
125-8824UK	KATANA ZR YML NA2 COLLAR / T:22MM
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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
125-8922UK	KATANA ZR HTML PLUS A1 COLLAR / T:14MM
125-8933UK	KATANA ZR HTML PLUS A1 COLLAR / T:18MM
125-8944UK	KATANA ZR HTML PLUS A1 COLLAR / T:22MM
125-8952UK	KATANA ZR HTML PLUS A2 COLLAR / T:14MM
125-8963UK	KATANA ZR HTML PLUS A2 COLLAR / T:18MM
125-8974UK	KATANA ZR HTML PLUS A2 COLLAR / T:22MM
125-8982UK	KATANA ZR HTML PLUS A3 COLLAR / T:14MM
125-8993UK	KATANA ZR HTML PLUS A3 COLLAR / T:18MM
125-9004UK	KATANA ZR HTML PLUS A3 COLLAR / T:22MM
125-9012UK	KATANA ZR HTML PLUS A3.5 COLLAR / T:14MM
125-9023UK	KATANA ZR HTML PLUS A3.5 COLLAR / T:18MM
125-9034UK	KATANA ZR HTML PLUS A3.5 COLLAR / T:22MM
125-9042UK	KATANA ZR HTML PLUS A4 COLLAR / T:14MM
125-9053UK	KATANA ZR HTML PLUS A4 COLLAR / T:18MM
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125-9072UK	KATANA ZR HTML PLUS B1 COLLAR / T:14MM
125-9083UK	KATANA ZR HTML PLUS B1 COLLAR / T:18MM

125-9094UK	KATANA ZR HTML PLUS B1 COLLAR / T:22MM
125-9102UK	KATANA ZR HTML PLUS B2 COLLAR / T:14MM
125-9113UK	KATANA ZR HTML PLUS B2 COLLAR / T:18MM
125-9124UK	KATANA ZR HTML PLUS B2 COLLAR / T:22MM
125-9132UK	KATANA ZR HTML PLUS B3 COLLAR / T:14MM
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125-9154UK	KATANA ZR HTML PLUS B3 COLLAR / T:22MM
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125-9173UK	KATANA ZR HTML PLUS C1 COLLAR / T:18MM
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125-9192UK	KATANA ZR HTML PLUS C2 COLLAR / T:14MM
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125-9214UK	KATANA ZR HTML PLUS C2 COLLAR / T:22MM
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125-9293UK	KATANA ZR HTML PLUS D3 COLLAR / T:18MM
125-9304UK	KATANA ZR HTML PLUS D3 COLLAR / T:22MM
125-9312UK	KATANA ZR HTML PLUS NW COLLAR / T:14MM
125-9323UK	KATANA ZR HTML PLUS NW COLLAR / T:18MM
125-9334UK	KATANA ZR HTML PLUS NW COLLAR / T:22MM
127-0055UK	Esthetic Colorant A plus 12ml
127-0065UK	Esthetic Colorant B plus 12ml
127-0075UK	Esthetic Colorant C plus 12ml
127-0085UK	Esthetic Colorant D plus 12ml
127-0095UK	Esthetic Colorant BROWN 12ml
127-0105UK	Esthetic Colorant ORANGE 12ml
127-0115UK	Esthetic Colorant GRAY 12ml
127-0125UK	Esthetic Colorant BLUE 12ml
127-0135UK	Esthetic Colorant VIOLET 12ml
127-0145UK	Esthetic Colorant PINK 12ml
127-0155UK	Esthetic Colorant WHITE 12ml
127-0165UK	Esthetic Colorant OPAQUE 12ml

127-0010EU	Esthetic Colorant Basic Kit
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