

## 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 1641:2009	Dentistry – Medical devices for dentistry - Materials
ISO 6872:2015	Dentistry – Ceramic materials
ISO 7405:2008	Dentistry –Evaluation of biocompatibility of medical devices used in dentistry
EN ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-3:2014	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity(reverse mutation test)
EN ISO 10993-6:2009	Biological evaluation of medical devices – Part 6: Tests for local effects after implantation
ISO10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
EN ISO 10993-14:2009	Biological evaluation of medical devices – Part 14: Identification and quantification of degradation products from ceramics
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 device

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

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

**Signature:**  Date: 2019. 7. 24

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
125-2273EU	KATANA ZR HT12 Collar / T:18MM
125-2284EU	KATANA ZR HT12 Collar/ T:22MM
125-2295EU	KATANA ZR HT12 Collar / T:26MM
125-7447EU	KATANA ZR HT12 Collar / T:30MM
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