

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: CERABIEN MiLai
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:


Name Satoshi Yamaguchi
Position President

Date: 25 / 5 / 2021

CERABIEN MiLai

Type	Product name
109-0010EU	CERABIEN MiLai MICRO LAYERING KIT (160G)
109-0020EU	CERABIEN MiLai INTERNAL STAIN KIT (45G)
109-0051EU	CERABIEN MiLai TX (10G)
109-0212EU	CERABIEN MiLai TX (50G)
109-0071EU	CERABIEN MiLai LTX (10G)
109-0232EU	CERABIEN MiLai LTX (50G)
109-0101EU	CERABIEN MiLai LT Royal Blue (10G)
109-0262EU	CERABIEN MiLai LT Royal Blue (50G)
109-0081EU	CERABIEN MiLai LT1 (10G)
109-0242EU	CERABIEN MiLai LT1 (50G)
109-0111EU	CERABIEN MiLai AQUA BLUE 2 (10G)
109-0272EU	CERABIEN MiLai AQUA BLUE 2 (50G)
109-0091EU	CERABIEN MiLai LT SUPER GRAY (10G)
109-0252EU	CERABIEN MiLai LT SUPER GRAY (50G)
109-0121EU	CERABIEN MiLai CREAMY ENAMEL (10G)
109-0282EU	CERABIEN MiLai CREAMY ENAMEL (50G)
109-0061EU	CERABIEN MiLai ELT1 (10G)
109-0222EU	CERABIEN MiLai ELT1 (50G)
109-0141EU	CERABIEN MiLai CCV-2 (10G)
109-0302EU	CERABIEN MiLai CCV-2 (50G)
109-0131EU	CERABIEN MiLai E2 (10G)
109-0292EU	CERABIEN MiLai E2 (50G)
109-0151EU	CERABIEN MiLai TISSUE 1 (10G)
109-0312EU	CERABIEN MiLai TISSUE 1 (50G)
109-0161EU	CERABIEN MiLai TISSUE 4 (10G)
109-0322EU	CERABIEN MiLai TISSUE 4 (50G)
109-0171EU	CERABIEN MiLai TISSUE 5 (10G)
109-0332EU	CERABIEN MiLai TISSUE 5 (50G)
109-0181EU	CERABIEN MiLai TISSUE 6 (10G)
109-0342EU	CERABIEN MiLai TISSUE 6 (50G)
109-0191EU	CERABIEN MiLai VALUE LINER 1 (10G)
109-0352EU	CERABIEN MiLai VALUE LINER 1 (50G)
109-0201EU	CERABIEN MiLai VALUE LINER 2 (10G)
109-0362EU	CERABIEN MiLai VALUE LINER 2 (50G)
109-0371EU	CERABIEN MiLai Internal Stain WHITE (3G)

109-0381EU	CERABIEN MiLai Internal Stain GRAY (3G)
109-0391EU	CERABIEN MiLai Internal Stain INCISAL BLUE 1 (3G)
109-0401EU	CERABIEN MiLai Internal Stain INCISAL BLUE 2 (3G)
109-0411EU	CERABIEN MiLai Internal Stain BLUE (3G)
109-0421EU	CERABIEN MiLai Internal Stain Yellow (3G)
109-0431EU	CERABIEN MiLai Internal Stain MAMELON ORANGE 2 (3G)
109-0441EU	CERABIEN MiLai Internal Stain CERVICAL 2 (3G)
109-0451EU	CERABIEN MiLai Internal Stain SALMON PINK (3G)
109-0461EU	CERABIEN MiLai Internal Stain TISSUE PINK (3G)
109-0471EU	CERABIEN MiLai Internal Stain TISSUE RED (3G)
109-0481EU	CERABIEN MiLai Internal Stain A+ (3G)
109-0491EU	CERABIEN MiLai Internal Stain B+ (3G)
109-0501EU	CERABIEN MiLai Internal Stain BRIGHT (3G)
109-0511EU	CERABIEN MiLai Internal Stain FLUORO (3G)
126-0111EU	IS LIQUID (10ML)
126-0122EU	IS LIQUID (100ML)
126-0232EU	LF LIQUID (100ML)
211-2589EU	C.G.801 CERABIEN MiLai
211-2599EU	CERABIEN MiLai COLOR GUIDE
109-0010UK	CERABIEN MiLai MICRO LAYERING KIT (160G)
109-0020UK	CERABIEN MiLai INTERNAL STAIN KIT (45G)
109-0051UK	CERABIEN MiLai TX (10G)
109-0212UK	CERABIEN MiLai TX (50G)
109-0071UK	CERABIEN MiLai LTX (10G)
109-0232UK	CERABIEN MiLai LTX (50G)
109-0101UK	CERABIEN MiLai Luster LT Royal Blue (10G)
109-0262UK	CERABIEN MiLai Luster LT Royal Blue (50G)
109-0081UK	CERABIEN MiLai LT1 (10G)
109-0242UK	CERABIEN MiLai LT1 (50G)
109-0111UK	CERABIEN MiLai AQUA BLUE 2 (10G)
109-0272UK	CERABIEN MiLai AQUA BLUE 2 (50G)
109-0091UK	CERABIEN MiLai LT SUPER GRAY (10G)
109-0252UK	CERABIEN MiLai LT SUPER GRAY (50G)
109-0121UK	CERABIEN MiLai CREAMY ENAMEL (10G)
109-0282UK	CERABIEN MiLai CREAMY ENAMEL (50G)
109-0061UK	CERABIEN MiLai ELT1 (10G)
109-0222UK	CERABIEN MiLai ELT1 (50G)

109-0141UK	CERABIEN MiLai CCV-2 (10G)
109-0302UK	CERABIEN MiLai CCV-2 (50G)
109-0131UK	CERABIEN MiLai E2 (10G)
109-0292UK	CERABIEN MiLai E2 (50G)
109-0151UK	CERABIEN MiLai TISSUE 1 (10G)
109-0312UK	CERABIEN MiLai TISSUE 1 (50G)
109-0161UK	CERABIEN MiLai TISSUE 4 (10G)
109-0322UK	CERABIEN MiLai TISSUE 4 (50G)
109-0171UK	CERABIEN MiLai TISSUE 5 (10G)
109-0332UK	CERABIEN MiLai TISSUE 5 (50G)
109-0181UK	CERABIEN MiLai TISSUE 6 (10G)
109-0342UK	CERABIEN MiLai TISSUE 6 (50G)
109-0191UK	CERABIEN MiLai VALUE LINER 1 (10G)
109-0352UK	CERABIEN MiLai VALUE LINER 1 (50G)
109-0201UK	CERABIEN MiLai VALUE LINER 2 (10G)
109-0362UK	CERABIEN MiLai VALUE LINER 2 (50G)
109-0371UK	CERABIEN MiLai Internal Stain WHITE (3G)
109-0381UK	CERABIEN MiLai Internal Stain GRAY (3G)
109-0391UK	CERABIEN MiLai Internal Stain INCISAL BLUE 1 (3G)
109-0401UK	CERABIEN MiLai Internal Stain INCISAL BLUE 2 (3G)
109-0411UK	CERABIEN MiLai Internal Stain BLUE (3G)
109-0421UK	CERABIEN MiLai Internal Stain Yellow (3G)
109-0431UK	CERABIEN MiLai Internal Stain MAMELON ORANGE 2 (3G)
109-0441UK	CERABIEN MiLai Internal Stain CERVICAL 2 (3G)
109-0451UK	CERABIEN MiLai Internal Stain SALMON PINK (3G)
109-0461UK	CERABIEN MiLai Internal Stain TISSUE PINK (3G)
109-0471UK	CERABIEN MiLai Internal Stain TISSUE RED (3G)
109-0481UK	CERABIEN MiLai Internal Stain A+ (3G)
109-0491UK	CERABIEN MiLai Internal Stain B+ (3G)
109-0501UK	CERABIEN MiLai Internal Stain BRIGHT (3G)
109-0511UK	CERABIEN MiLai Internal Stain FLUORO (3G)
126-0111UK	IS LIQUID (10ML)
126-0122UK	IS LIQUID (100ML)
126-0232UK	LF LIQUID (100ML)

Addendum to the original Declaration of Conformity

Name of device: CERABIEN MiLai

Per 01 November 2021, the EU Authorized Representative as listed on the original DoC has changed.

OLD AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Kuraray Europe GmbH	Philipp-Reis-Str.4, 65795 Hattersheim am Main, Germany	+49.(0)69.305.35835 – phone

NEW AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague, The Netherlands	+31.70.345.8570 - phone EmergoEurope@ul.com

DATE: 01/11/2021

Per 31 January 2023, the address of our EU Authorized Representative as listed on the original DoC has changed.

OLD ADDRESS AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague, The Netherlands	+31.70.345.8570 - phone EmergoEurope@ul.com

NEW ADDRESS AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Emergo Europe	Westervoortsedijk 60 6827 AT Arnhem, The Netherlands	+31.70.345.8570 - phone EmergoEurope@ul.com

DATE: 31/01/2023

COLOR GUIDE has removed from the Product list.

ON THE OLD PRODUCT LIST	
Type	Product name
211-2589EU	C.G.801 CERABIEN MiLai
211-2599EU	CERABIEN MiLai COLOR GUIDE

ON THE NEW PRODUCT LIST	
Type	Product name
Removed	Removed
Removed	Removed

DATE: 30/06/2023

UK Type has been unified to EU Type.

Product name correction

OLD PRODUCT LIST	
Type	Product name
Refer to the attachment	Refer to the attachment

NEW PRODUCT LIST	
Type	Product name
Refer to the attachment	Refer to the attachment

DATE: 10/11/2023

Addition/update of standard

OLD APPLIED STANDARDS
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, EN ISO 14971 :2012,

NEW APPLIED STANDARDS
EN ISO 13485: 2016/AC: 2018, EN 1641: 2009, ISO 9693:2019, ISO 6872:2015, ISO 7405:2018, EN ISO 10993-1:2020, MEDDEV.2.7.1 Rev.4, EN ISO 15223-1:2021, ISO 20417:2021, EN ISO 14971:2019+A11:2021,

DATE: 10/11/2023

COMPANY REPRESENTATIVE: Satoshi Yamaguchi

TITLE: President

SIGNATURE:

山口 里志

DATE: 28/03/2024

CERABIEN MiLai OLD PRODUCT LIST

Type	Product name
109-0010EU	CERABIEN MiLai MICRO LAYERING KIT (160G)
109-0020EU	CERABIEN MiLai INTERNAL STAIN KIT (45G)
109-0051EU	CERABIEN MiLai TX (10G)
109-0212EU	CERABIEN MiLai TX (50G)
109-0071EU	CERABIEN MiLai LTX (10G)
109-0232EU	CERABIEN MiLai LTX (50G)
109-0101EU	CERABIEN MiLai LT Royal Blue (10G)
109-0262EU	CERABIEN MiLai LT Royal Blue (50G)
109-0081EU	CERABIEN MiLai LT1 (10G)
109-0242EU	CERABIEN MiLai LT1 (50G)
109-0111EU	CERABIEN MiLai AQUA BLUE 2 (10G)
109-0272EU	CERABIEN MiLai AQUA BLUE 2 (50G)
109-0091EU	CERABIEN MiLai LT SUPER GRAY (10G)
109-0252EU	CERABIEN MiLai LT SUPER GRAY (50G)
109-0121EU	CERABIEN MiLai CREAMY ENAMEL (10G)
109-0282EU	CERABIEN MiLai CREAMY ENAMEL (50G)
109-0061EU	CERABIEN MiLai ELT1 (10G)
109-0222EU	CERABIEN MiLai ELT1 (50G)
109-0141EU	CERABIEN MiLai CCV-2 (10G)
109-0302EU	CERABIEN MiLai CCV-2 (50G)
109-0131EU	CERABIEN MiLai E2 (10G)
109-0292EU	CERABIEN MiLai E2 (50G)
109-0151EU	CERABIEN MiLai TISSUE 1 (10G)
109-0312EU	CERABIEN MiLai TISSUE 1 (50G)
109-0161EU	CERABIEN MiLai TISSUE 4 (10G)
109-0322EU	CERABIEN MiLai TISSUE 4 (50G)
109-0171EU	CERABIEN MiLai TISSUE 5 (10G)
109-0332EU	CERABIEN MiLai TISSUE 5 (50G)
109-0181EU	CERABIEN MiLai TISSUE 6 (10G)
109-0342EU	CERABIEN MiLai TISSUE 6 (50G)
109-0191EU	CERABIEN MiLai VALUE LINER 1 (10G)
109-0352EU	CERABIEN MiLai VALUE LINER 1 (50G)
109-0201EU	CERABIEN MiLai VALUE LINER 2 (10G)
109-0362EU	CERABIEN MiLai VALUE LINER 2 (50G)
109-0371EU	CERABIEN MiLai Internal Stain WHITE (3G)

109-0381EU	CERABIEN MiLai Internal Stain GRAY (3G)
109-0391EU	CERABIEN MiLai Internal Stain INCISAL BLUE 1 (3G)
109-0401EU	CERABIEN MiLai Internal Stain INCISAL BLUE 2 (3G)
109-0411EU	CERABIEN MiLai Internal Stain BLUE (3G)
109-0421EU	CERABIEN MiLai Internal Stain Yellow (3G)
109-0431EU	CERABIEN MiLai Internal Stain MAMELON ORANGE 2 (3G)
109-0441EU	CERABIEN MiLai Internal Stain CERVICAL 2 (3G)
109-0451EU	CERABIEN MiLai Internal Stain SALMON PINK (3G)
109-0461EU	CERABIEN MiLai Internal Stain TISSUE PINK (3G)
109-0471EU	CERABIEN MiLai Internal Stain TISSUE RED (3G)
109-0481EU	CERABIEN MiLai Internal Stain A+ (3G)
109-0491EU	CERABIEN MiLai Internal Stain B+ (3G)
109-0501EU	CERABIEN MiLai Internal Stain BRIGHT (3G)
109-0511EU	CERABIEN MiLai Internal Stain FLUORO (3G)
126-0111EU	IS LIQUID (10ML)
126-0122EU	IS LIQUID (100ML)
126-0232EU	LF LIQUID (100ML)
211-2589EU	C.G.801 CERABIEN MiLai
211-2599EU	CERABIEN MiLai COLOR GUIDE
109-0010UK	CERABIEN MiLai MICRO LAYERING KIT (160G)
109-0020UK	CERABIEN MiLai INTERNAL STAIN KIT (45G)
109-0051UK	CERABIEN MiLai TX (10G)
109-0212UK	CERABIEN MiLai TX (50G)
109-0071UK	CERABIEN MiLai LTX (10G)
109-0232UK	CERABIEN MiLai LTX (50G)
109-0101UK	CERABIEN MiLai Luster LT Royal Blue (10G)
109-0262UK	CERABIEN MiLai Luster LT Royal Blue (50G)
109-0081UK	CERABIEN MiLai LT1 (10G)
109-0242UK	CERABIEN MiLai LT1 (50G)
109-0111UK	CERABIEN MiLai AQUA BLUE 2 (10G)
109-0272UK	CERABIEN MiLai AQUA BLUE 2 (50G)
109-0091UK	CERABIEN MiLai LT SUPER GRAY (10G)
109-0252UK	CERABIEN MiLai LT SUPER GRAY (50G)
109-0121UK	CERABIEN MiLai CREAMY ENAMEL (10G)
109-0282UK	CERABIEN MiLai CREAMY ENAMEL (50G)
109-0061UK	CERABIEN MiLai ELT1 (10G)
109-0222UK	CERABIEN MiLai ELT1 (50G)

109-0141UK	CERABIEN MiLai CCV-2 (10G)
109-0302UK	CERABIEN MiLai CCV-2 (50G)
109-0131UK	CERABIEN MiLai E2 (10G)
109-0292UK	CERABIEN MiLai E2 (50G)
109-0151UK	CERABIEN MiLai TISSUE 1 (10G)
109-0312UK	CERABIEN MiLai TISSUE 1 (50G)
109-0161UK	CERABIEN MiLai TISSUE 4 (10G)
109-0322UK	CERABIEN MiLai TISSUE 4 (50G)
109-0171UK	CERABIEN MiLai TISSUE 5 (10G)
109-0332UK	CERABIEN MiLai TISSUE 5 (50G)
109-0181UK	CERABIEN MiLai TISSUE 6 (10G)
109-0342UK	CERABIEN MiLai TISSUE 6 (50G)
109-0191UK	CERABIEN MiLai VALUE LINER 1 (10G)
109-0352UK	CERABIEN MiLai VALUE LINER 1 (50G)
109-0201UK	CERABIEN MiLai VALUE LINER 2 (10G)
109-0362UK	CERABIEN MiLai VALUE LINER 2 (50G)
109-0371UK	CERABIEN MiLai Internal Stain WHITE (3G)
109-0381UK	CERABIEN MiLai Internal Stain GRAY (3G)
109-0391UK	CERABIEN MiLai Internal Stain INCISAL BLUE 1 (3G)
109-0401UK	CERABIEN MiLai Internal Stain INCISAL BLUE 2 (3G)
109-0411UK	CERABIEN MiLai Internal Stain BLUE (3G)
109-0421UK	CERABIEN MiLai Internal Stain Yellow (3G)
109-0431UK	CERABIEN MiLai Internal Stain MAMELON ORANGE 2 (3G)
109-0441UK	CERABIEN MiLai Internal Stain CERVICAL 2 (3G)
109-0451UK	CERABIEN MiLai Internal Stain SALMON PINK (3G)
109-0461UK	CERABIEN MiLai Internal Stain TISSUE PINK (3G)
109-0471UK	CERABIEN MiLai Internal Stain TISSUE RED (3G)
109-0481UK	CERABIEN MiLai Internal Stain A+ (3G)
109-0491UK	CERABIEN MiLai Internal Stain B+ (3G)
109-0501UK	CERABIEN MiLai Internal Stain BRIGHT (3G)
109-0511UK	CERABIEN MiLai Internal Stain FLUORO (3G)
126-0111UK	IS LIQUID (10ML)
126-0122UK	IS LIQUID (100ML)
126-0232UK	LF LIQUID (100ML)

CERABIEN MiLai NEW PRODUCT LIST

Type	Product name
109-0010EU	CERABIEN MiLai MICRO LAYERING KIT
109-0020EU	CERABIEN MiLai INTERNAL STAIN KIT
109-0051EU	CERABIEN MiLai T _X (10G)
109-0212EU	CERABIEN MiLai T _X (50G)
109-0071EU	CERABIEN MiLai LT _X (10G)
109-0232EU	CERABIEN MiLai LT _X (50G)
109-0101EU	CERABIEN MiLai LT Royal Blue (10G)
109-0262EU	CERABIEN MiLai LT Royal Blue (50G)
109-0081EU	CERABIEN MiLai LT ₁ (10G)
109-0242EU	CERABIEN MiLai LT ₁ (50G)
109-0111EU	CERABIEN MiLai Aqua Blue 2 (10G)
109-0272EU	CERABIEN MiLai Aqua Blue 2 (50G)
109-0091EU	CERABIEN MiLai LT Super Gray (10G)
109-0252EU	CERABIEN MiLai LT Super Gray (50G)
109-0121EU	CERABIEN MiLai Creamy Enamel (10G)
109-0282EU	CERABIEN MiLai Creamy Enamel (50G)
109-0061EU	CERABIEN MiLai ELT ₁ (10G)
109-0222EU	CERABIEN MiLai ELT ₁ (50G)
109-0141EU	CERABIEN MiLai CCV-2 (10G)
109-0302EU	CERABIEN MiLai CCV-2 (50G)
109-0131EU	CERABIEN MiLai E ₂ (10G)
109-0292EU	CERABIEN MiLai E ₂ (50G)
109-0151EU	CERABIEN MiLai Tissue 1 (10G)
109-0312EU	CERABIEN MiLai Tissue 1 (50G)
109-0161EU	CERABIEN MiLai Tissue 4 (10G)
109-0322EU	CERABIEN MiLai Tissue 4 (50G)
109-0171EU	CERABIEN MiLai Tissue 5 (10G)
109-0332EU	CERABIEN MiLai Tissue 5 (50G)
109-0181EU	CERABIEN MiLai Tissue 6 (10G)
109-0342EU	CERABIEN MiLai Tissue 6 (50G)
109-0191EU	CERABIEN MiLai Value Liner 1 (10G)
109-0352EU	CERABIEN MiLai Value Liner 1 (50G)
109-0201EU	CERABIEN MiLai Value Liner 2 (10G)
109-0362EU	CERABIEN MiLai Value Liner 2 (50G)
109-0371EU	CERABIEN MiLai Internal Stain White (3G)

109-0381EU	CERABIEN MiLai Internal Stain Gray (3G)
109-0391EU	CERABIEN MiLai Internal Stain Incisal Blue 1 (3G)
109-0401EU	CERABIEN MiLai Internal Stain Incisal Blue 2 (3G)
109-0411EU	CERABIEN MiLai Internal Stain Blue (3G)
109-0421EU	CERABIEN MiLai Internal Stain Yellow (3G)
109-0431EU	CERABIEN MiLai Internal Stain Mamelon Orange 2 (3G)
109-0441EU	CERABIEN MiLai Internal Stain Cervical 2 (3G)
109-0451EU	CERABIEN MiLai Internal Stain Salmon Pink (3G)
109-0461EU	CERABIEN MiLai Internal Stain Tissue Pink (3G)
109-0471EU	CERABIEN MiLai Internal Stain Tissue Red (3G)
109-0481EU	CERABIEN MiLai Internal Stain A ⁺ (3G)
109-0491EU	CERABIEN MiLai Internal Stain B ⁺ (3G)
109-0501EU	CERABIEN MiLai Internal Stain Bright (3G)
109-0511EU	CERABIEN MiLai Internal Stain Fluoro (3G)
126-0111EU	CERABIEN MiLai IS LIQUID (10ML)
126-0122EU	CERABIEN MiLai IS LIQUID (100ML)
126-0232EU	LF LIQUID (100ML)