EC Certificate Full Quality Assurance System: Certificate JP19/040488

The management system of

Kuraray Noritake Dental Inc.

300 Higashiyama, Miyoshi-cho, Miyoshi,
Aichi, 470-0293 Japan

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Dental Porcelain and Dental Ceramic Block for Prosthetic Restoration

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 01 May 2020 until 24 October 2023
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 19 October 2006
and first certified by SGS Belgium NV since 24 July 2019

Certification is based on reports numbered JP/YOK 4321

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

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Kuraray Noritake Dental Inc.
300 Higashiyama, Miyoshi-cho, Miyoshi,
Aichi, 470-0293
Japan

4 Aug 2023

Confirmation Letter Reference: CLNB1639 – JP/YOK/4321

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer

Kuraray Noritake Dental Inc.
300 Higashiyama, Miyoshi-cho, Miyoshi,
Aichi, 470-0293
Japan
SRN Number (if available): JP-MF-000017328

Authorized representative:
Emergo Europe
B.V.Westervoortsedijk 60,
6827 AT Arnhem,
The Netherlands
SRN Number (if available): NL-AR-000000116

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15th March 2023, this letter also confirms that:

- The manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;

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- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices
- 31st December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV 1639,

Pp[Sean Kelly]
Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone: +41 22 739 98 58

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Devices covered by this letter:

Device name / Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Dental Ceramic Block / Basic UDI-DI: 457121511CERAMICBLOCK2T	Class IIa	N/A	JP19/040488

Device name / Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Dental Porcelain / Basic UDI-DI: 457121511PORCELAINCB	Class IIa	N/A	JP19/040488

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/07/28	Version 1	Initial issue

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Manufacturer's Declaration to Regulation (EU) 2023/607

According to Regulation (EU)2017/745 (MDR) and regarding the transitional provisions Kuraray Noritake Dental Inc. (Miyoshi) declares the amendments to Article 120 of the MDR, as amended by Regulation (EU) 2023/607 applies to the following device(s):

Manufacturer name:	Kuraray Noritake Dental Inc.
Manufacturer address and contact details:	300 Higashiyama, Miyoshi-cho, Miyoshi, Aichi, 470-0293 Japan
Single Registration Number (SRN) (if available):	JP-MF-000017328

Authorised Representative name	Emergo Europe B.V.
Authorised Representative address and contact details	Westervoortsedijk 60, 6827 AT, Arnhem THE NETHERLANDS
Single Registration Number (SRN)	NL-AR-000000116

Notified body name (if applicable)	SGS Belgium NV ☒ See attached schedule
Notified body number (if applicable)	1639 ☒ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	JP19/040488 ☒ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2023-10-24 ☒ See attached schedule
End date of extended validity/transition period	2028-12-31 ☒ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[1]

- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023

- *Choose applicable statements:*

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request)

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  ☒ Expired/expires *after* 20 March 2023:

  ☒ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

- **Up-classified devices**

  In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

  Choose one applicable statement:

  ☐ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

- **Quality Management System (QMS)**

  - *Choose one applicable statement:*

    ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

    ☒ A QMS in accordance with Article 10(9) MDR is in place.

    ☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

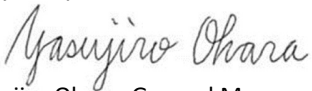
- **Device(s) as listed in the attached schedule**

  - The device(s) continue to comply with the AIMDD or MDD.
  - The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
  - The device(s) do not present an unacceptable risk to health or safety of patients, users, or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: Kuraray Noritake Dental Inc.

Location & Date: Tokyo, Japan, 2023-09-05

Signature, Print Name, Title: 

Yasujiro Ohara, General Manager of Quality Assurance Department

kuraray

Noritake

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Device identification *(e.g., device name, family / group name device model or catalogue number)*	**Directive Certificate number(s) to which this confirmation is made** □ *Not applicable*	**Original expiry date**[2] □ *Not applicable*	**Notified Body name and number** □ *Not applicable*	**Classification and rule under the MDR**	**End date of extended validity / transition period**	**Substitute Device** ☒ *Not applicable*
Dental Porcelain	JP19/040488	2023-10-24	SGS Belgium NV 1639	IIa Rule 8	2028-12-31	N/A
Dental Ceramic Block	JP19/040488	2023-10-24	SGS Belgium NV 1639	IIa Rule 8	2028-12-31	N/A

[2] As indicated on the Directive Certificate prior to the extension of the validity.