



Tokuyama Dental Corporation  
38-9, Taitou 1-chome, Taitou-ku  
Tokyo 110-0016  
Japan

16 February 2024

**Confirmation Letter Reference: CLNB1639 – JP/YOK/8787**

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

Company Name  
Tokuyama Dental Corporation  
38-9, Taitou 1-chome, Taitou-ku  
Tokyo 110-0016  
Japan  
SRN Number: JP-MF-000033625

Authorized representative  
Tokuyama Dental Italy S.r.l.  
Via Chizzalunga, 1  
36066 Sandrigo, Vicenza  
Italy  
SRN Number: IT-AR-000021265

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 15<sup>th</sup> 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;

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 May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.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

- 26<sup>th</sup> May 2026 for Class III custom-made implantable devices
- 31<sup>st</sup> 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)
- 31<sup>st</sup> December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31<sup>st</sup> 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 [Haldun OGUZ]

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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
PROTECTIVE SEALANT Basic UDI-DI;4548190DS01YY	Class IIa	N/A	P19/040508 NB1639
TOKUYAMA EE-BOND Basic UDI-DI; 4548190DA03WA	Class IIa	N/A	P19/040508 NB1639
ONE-UP BOND F	Class IIa	N/A	P19/040508 NB1639

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
Basic UDI-DI; 4548190DA01W6			
TOKUYAMA UNIVERSAL BOND II Basic UDI-DI; 4548190DA02W8	Class IIa	N/A	P19/040508 NB1639
ESTECEM II PLUS Basic UDI-DI; 4548190DC01WG	Class IIa	N/A	P19/040508 NB1639
OMNICHROMA Basic UDI-DI; 4548190DCRM02QT	Class IIa	N/A	P19/040508 NB1639
OMNICHROMA FLOW Basic UDI-DI; 4548190DCRM03QV	Class IIa	N/A	P19/040508 NB1639
PALFIQUE ESTELITE Basic UDI-DI; 4548190DCRM01QR	Class IIa	N/A	P19/040508 NB1639

#### Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
16 February 2024	Version 1	Initial Issue