META BIOMED CO., LTD.
270 Osongsaengmyeong1-ro, Osong-eup, Heungdeok-gu, Cheongju-si,
Chungcheongbuk-do, 28161
Republic of Korea
SRN: KR-MF-000009681

May 20, 2024

Confirmation Letter Reference: CLNB1639 - WW/PCI/208838

To whom it may concern,

Confirmation of receipt of the status of a formal application, written agreement, and appropriate surveillance 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

Manufacturer
META BIOMED CO., LTD.
270 Osongsaengmyeong1-ro, Osong-eup, Heungdeok-gu, Cheongju-si,
Chungcheongbuk-do, 28161
Republic of Korea
SRN: KR-MF-000009681

Authorized representative
Meta Biomed Europe GmbH
Wiesenstr., 35
45473 Mülheim an der Ruhr
Germany
SRN: DE-AR-000004953

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the

NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- The manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry;
- 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after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.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 NB1639,

Ian How
PP
Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone: +41 22 739 98 58

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive**:**

Device name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denominatio n is not obvious)	If the MDR device is a substitute device, identification of the correspondin g MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Sterile Absorbent Paper Points (Brand: Absorbent Paper Points Blister Pack) Basic UDI-DI: 880638780033KR;	Class IIa		N/A	CE1639 KR19/81826259
Sterile Absorbent Paper Points (Brand: Absorbent Paper Points) Basic UDI-DI: 880638780001KC	Class IIa		N/A	CE1639 KR19/81826259
Calcium Hydroxide Temporary Filling Material (Brand: Metapaste) Basic UDI-DI: 880638780005KL	Class IIa		N/A	CE1639 KR19/81826259
Calcium Hydroxide Temporary Filling Material (Brand: Metapaste Plus) Basic UDI-DI: 880638780032KP	Class IIa		N/A	CE1639 KR19/81826259
Hydraulic Temporary Restorative Material (Brand: MD-Temp Plus) Basic UDI-DI: 880638780007KQ	Class IIa		N/A	CE1639 KR19/81826259

Device name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denominatio n is not obvious)	If the MDR device is a substitute device, identification of the correspondin g MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Root Canal Cleaning and Smear Layer Removing Solution (Brand: MD-Cleanser) Basic UDI-DI: 880638780012KH	Class IIa		N/A	CE1639 KR19/81826259
Root Canal Cleaning and Smear Layer Removing Solution (Brand: MD-ChelCream) Basic UDI-DI: 880638780013KK	Class IIa		N/A	CE1639 KR19/81826259
Dental Temporary Cement (Brand: NETC) Basic UDI-DI: 880638780017KT	Class IIa		N/A	CE1639 KR19/81826259
Dental Etchant (Brand: Meta Etchant) Basic UDI-DI: 880638780018KV	Class IIa		N/A	CE1639 KR19/81826259
Dental Root-Canal Obturating Materials (Brand: Gutta Percha Points) Basic UDI-DI: 880638780002KE	Class IIa		N/A	CE1639 KR19/81826259

Device name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denominatio n is not obvious)	If the MDR device is a substitute device, identification of the correspondin g MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Dental Root-Canal Obturating Materials (Brand: Gutta Percha Bar Plus) Basic UDI-DI: 880638780004KJ	Class IIa		N/A	CE1639 KR19/81826259
Dental Root-Canal Obturating Materials (Brand: Gutta Percha Points-S) Basic UDI-DI: 880638780003KG	Class IIa		N/A	CE1639 KR19/81826259
Resin Based Root Canal Sealer (Brand: ADSEAL) Basic UDI-DI: 880638780008KS	Class IIa		N/A	CE1639 KR19/81826259
Resin Based Root Canal Sealer (Brand: ADSEAL Plus) Basic UDI-DI: 880638780009KU	Class IIa		N/A	CE1639 KR19/81826259
Bioceramic Root Canal Sealer (Brand: CeraSeal) Basic UDI-DI: 880638780010KD	Class IIa		N/A	CE1639 KR19/81826259
Dental Resin Cement (Brand: Metacem) Basic UDI-DI: 880638780019KX	Class IIa		N/A	CE1639 KR19/81826259

Device name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denominatio n is not obvious)	If the MDR device is a substitute device, identification of the correspondin g MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Dental Adhesive (Brand: Meta P&Bond) Basic UDI-DI: 880638780020KG	Class IIa		N/A	CE1639 KR19/81826259
Dental Adhesive (Brand: EZ Bond Universal) Basic UDI-DI: 880638780031KM	Class IIa		N/A	CE1639 KR19/81826259
Dental Composite Resin (Brand: Nexcomp Flow) Basic UDI-DI: 880638780023KN	Class IIa		N/A	CE1639 KR19/81826259
Dental Composite Resin (Brand: NexCore) Basic UDI-DI: 880638780024KQ	Class IIa		N/A	CE1639 KR19/81826259
Dental Composite Resin (Brand: Ezfil) Basic UDI-DI: 880638780022KL	Class IIa		N/A	CE1639 KR19/81826259
Dental Composite Resin (Brand: Jet Flow Bulk) Basic UDI-DI: 880638785894NQ	Class IIa		N/A	CE1639 KR19/81826259

Device name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denominatio n is not obvious)	If the MDR device is a substitute device, identification of the correspondin g MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Dental Light Curing Cavity Liner (Brand: Biner LC) Basic UDI-DI: 880638780025KS	Class IIa		N/A	CE1639 KR19/81826259
Premixed Bioceramic Putty for Root Canal Repair (Brand: CeraPutty) Basic UDI-DI: 880638784917N4	Class IIa		N/A	CE1639 KR19/81826259

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	**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**
N/A			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/20	Version 1	Initial issue