



META SYSTEMS CO., LTD. also doing business as S-Denti Co., Ltd.
#1214-18, Sicox tower, 484, Dunchon-daero, Seongnam-si
Gyeonggi-do, 13229
Republic of Korea
SRN: KR-MF-000022945

Jan 14, 2025

Confirmation Letter Reference: CLNB1639 - WW/PCI/212119

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 SYSTEMS CO., LTD. also doing business as S-Denti Co., Ltd.
#1214-18, Sicox tower, 484, Dunchon-daero, Seongnam-si
Gyeonggi-do, 13229
Republic of Korea
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Authorized representative

Meta Biomed Europe GmbH
Schederhofstraße 59,
45145 Essen
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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.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,

Signed by:
Tony Lima
1C238A1020D64A6...

Virginie SILORET
Global Medical Device Certification Manager
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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 denomination is not obvious)	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 Root Canal Obturating Materials (Model: GUTTA PERCHA CARTRIDGE) Basic UDI-DI: 880945560005K9	Class IIa	N/A	N/A	NB1639 KR19/81826314
Endodontic Obturation System (Model: EQ-V and elements IC) Basic UDI-DI: 880945560002K3	Class IIa	Endodontic Obturation System including Pack, Fill, Pack tip and Fill needle	N/A	NB1639 KR19/81826314
Electronic Apex Locator for measuring the working length of the tooth in endodontic treatment (Model: EQ-PEX and Apex ID) Basic UDI-DI: 880945560001JZ	Class IIa	N/A	N/A	NB1639 KR19/81826314
Sonic Powered Endo Irrigation (Model: EQ-S) Basic UDI-DI: 880945560003K5	Class IIa	N/A	N/A	NB1639 KR19/81826314

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 denomination is not obvious)	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
Endodontic Motor including Contra angle handpiece (Model: EQ-M) Basic UDI-DI: 880945560004K7	Class IIa	Dental Endo Motor including Contra angle handpiece	N/A	NB1639 KR19/81826314

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 - All device are covered by NB1639 surveillance audit	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/09	Version 1	Initial issue
2025/01/14	Version 2	Second issue – Authorized representative address changed