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

11 Dec 2023

**Confirmation Letter Reference: CLNB1639 – WW/PCI/212119**

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

**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, Korea
SRN Number: KR-MF-000026311

**Authorized representative**
Wiesenstraße 35
45473 Mülheim an der Ruhr
Germany
SRN Number: DE-AR-000004953

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:

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- The manufacturer submitted the MDR application and signed the written agreement 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after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.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 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 Root Canal Obturating Materials | Class IIa | N/A | Certificate KR19/81826314; 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 |
|---|---|---|---|
| (Model: GUTTA PERCHA CARTRIDGE)<br><br>Basic UDI-DI: 880945560005K9 | | | |
| Endodontic Obturation System (Model: EQ-V)<br><br>Basic UDI-DI: 880945560002K3 | Class IIa | N/A | Certificate KR19/81826314; NB1639 |
| Endodontic Obturation System (Model: Elements IC)<br><br>Basic UDI-DI: 880945560002K3 | Class IIa | N/A | Certificate KR19/81826314; NB1639 |
| Electronic Apex Locator for measuring the working length of the tooth in endodontic treatment (Model: Apex ID)<br><br>Basic UDI-DI: 880945560001JZ | Class IIa | N/A | Certificate KR19/81826314; NB1639 |
| Electronic Apex Locator for measuring the working length of the tooth in endodontic treatment (Model: EQ-PEX)<br><br>Basic UDI-DI: 880945560001JZ | Class IIa | N/A | Certificate KR19/81826314; NB1639 |
| Sonic Powered Endo Irrigation (Model: EQ- | Class IIa | N/A | Certificate KR19/81826314; NB1639 |

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| **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 |
|---|---|---|---|
| S)<br><br>Basic UDI-DI: 880945560003K5 | | | |
| Endodontic Motor including Contra angle handpiece (Model: EQ-M)<br><br>Basic UDI-DI: 880945560004K7 | Class IIa | N/A | Certificate KR19/81826314; NB1639 |

Confirmation Letter Revision History

| Date | NB internal reference traceable to each version of the letter | Action |
|---|---|---|
| 2024/01/05 | Version 1 | Initial issue |
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