EC Certificate Full Quality Assurance System: Certificate KR19/81826227

The management system of

# MICRO-NX Co.,Ltd.

22, Maeyeo-ro 1gil, Dong-gu, Daegu, 41059, Korea

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

**Electric Micromotor and Control Unit for Dental Handpiece (NXHW-100E, NXOP-100E, EL-B40M, EL-B40I, EL-B40L, EL-B40S, MH-P400, EL-M40C, EL-M40S, EL-M40HS, EL-M40BA, EL-M40TT); Dental Torque Driver for Implant Surgery (MEG-TORQ, OSM-TORQ); Dental Engine for Implant Surgery (Model: ISE-170, ISE-170L, ISE-170C, ISE-270M, ISE-270C).**

**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 16 December 2019 until 10 June 2023
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 10 June 2015
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered KR/SEL Y-PC/14366

Authorised by

SGS Belgium NV, Notified Body 1639
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MICRO-NX Co., Ltd.
22, Maeyeo-ro 1-gil, Dong-gu
Daegu, 41059
Republic of Korea
SRN: KR-MF-000026311

June 3, 2024

**Confirmation Letter Reference: CLNB1639 - KR/SEL/Y-PC/14366**

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**
MICRO-NX Co., Ltd.
22, Maeyeo-ro 1-gil, Dong-gu
Daegu, 41059
Republic of Korea
SRN: KR-MF-000026311

**Authorized representative**
JaviTech e.K.
Sachsenhausener Str. 16
65824 Schwalbach a. Ts.
Germany
SRN: DE-AR-000005875

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 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 Engine for Implant Surgery<br>(Model: ISE-170, ISE-170L, ISE-170C, ISE-270M, ISE-270C)<br><br>Basic UDI-DI: 88000296ISE-270MFK | Class IIa | N/A | N/A | NB1639<br>KR19/81826227 |
| Dental Handpiece (Model: SG200, SG200L, CA100R, CA100L, SA100R, SA100L, CA160, CA160L)<br><br>Basic UDI-DI: 88000296SG200LB5 | Class IIa | Non-sterile dental handpiece | | NB1639<br>KR19/81826227<br><br>NB2195<br>2195-MED-2031401 |
| Dental Torque Driver for Implant Surgery (Model: MEG-TORQ, OSM-TORQ)<br><br>Basic UDI-DI: 88000296TD-C60B4 | Class IIa | N/A | N/A | NB1639<br>KR19/81826227 |
| Micromotor Control Unit for Dental Handpiece (Model: EL-M40S, EL-M40C, EL-M40BA, EL-M40HS, EL-M40TT)<br><br>Basic UDI-DI: 8800029600EL-M40SXC | Class IIa | Electric Micromotor and Control Unit for Dental Handpiece | | NB1639<br>KR19/81826227 |

| **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 |
|---|---|---|---|---|
| Electric Micromotor for Dental Handpiece (Model: NXOP-100E, NXHW-100E, EL-B40S, EL-B40L, EL-B40I, EL-B40M)<br><br>Basic UDI-DI: 88000296EL-B40S58 | Class IIa | Electric Micromotor and Control Unit for Dental Handpiece | N/A | NB1639<br>KR19/81826227 |

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 |
|---|---|---|
| 2023/05/23 | Version 1 | Initial issue |
| 2023/05/30 | Version 2 | Revised devices covered by the letter |
| 2024/06/03 | Version 3 | Revised devices covered by the letter |