

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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