

EC Declaration of Conformity

We herewith declare that the under-mentioned products are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by Directive 2007/47/EC. All supporting documentation is retained under the premises of the manufacturer.

Product Name: Micromotor Control Unit for Dental Handpiece
Model Name: EL-M40S

Classification : Class IIa (Annex IX Rule 9, Council Directive 93/42/EEC as amended by Directive 2007/47/EC)

Conformity Assessment Route : Annex II, Excluding Section 4, Council Directive 93/42/EEC as amended by Directive 2007/47/EC

Notified Body : SGS Belgium NV [Notified Body No. 1639]
SGS House Noorderlaan 87 2030 Antwerp Belgium

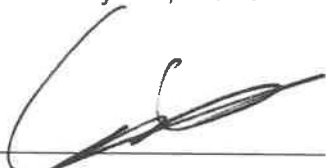
Applied Standards : EN ISO 13485:2012/AC:2012, EN ISO 14971:2012, EN980:2008, EN1041:2008, EN 60601-1:2006, EN 60601-1-2:2007, EN 60601-1-6:2010, EN 62366:2008, IEC62471:2006, IEC 80601-2-60:2012, ISO3964:1982, ISO7494-1:2011, ISO ISO14457:2012, EN62304:2006/AC:2008, EN1640:2009, MEDDEV 2.7.1/Rev.4, MEDDEV 2.12.1/Rev.8, MEDDEV 2.12.2/Rev.2

EC Representative : MICRO-NX branch office
Karl-Marx-str 6 ; 16540 Hohen neuendorf Germany
Tel.0176/20395876

EC Certificate : KR19/81826227 (2023-06-10)

GMDN Code : 38763

Date: February 18, 2020



Jong-Kun, Lee / President



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Product Name: Electric Micromotor for Dental Handpiece

Model Name: EL-B40S, EL-B40L, EL-B40I, EL-B40M, NXHW-100E, NXOP-100E

Classification : Class IIa (Annex IX Rule 9, Council Directive 93/42/EEC as amended by Directive 2007/47/EC)

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