

EC Declaration of Conformity

according to the Medical Devices Directive 93/42/EEC

For the following medical device :

Product Name : CORDLESS ENDODONTIC MOTOR
(Dental endo motor including contra angle handpiece)

Brand Name : Elements Connect

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

Manufacturer's Name : Meta Systems Co., Ltd.

Manufacturer's Address : #1214-18, Sicox tower 12F, 484, Dunchon-daero, Jungwon-gu,
Seongnam-si, Gyeonggi-do, 13229, Korea

is herewith the conformity with the requirements set out in the Council Directive 93/42/EEC of 14 June 1993 as amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 concerning Medical Devices declared, For the evaluation of the conformity with this Directive, the following standards have been applied:

EN ISO 14971:2019, IEC 60601-1:2005 +A1:2012, IEC 80601-2-60:2019, IEC 60601-1-2:2014,
EN 60601-1-6: 2010, EN 62366: 2008, EN 62304: 2006, IEC 62133:2012, EN ISO 15223-1:2016,
EN 1041: 2008, ISO 7010: 2020, ISO 7405:2018, EN ISO 10993-1: 2018, EN ISO 10993-5: 2009,
EN ISO 10993-10: 2013, EN ISO 13485:2016, ISO 11737-1: 2018, ISO 11737-2: 2019,
EN ISO 17664:2004, ANSI/AAMI ST79:2017, ISO 14457:2017, ISO 1797-1:2011, MEDDEV 2.7.1 (Rev.4)

is subject to the procedure set out in Annex II(excluding section 4) of Directive 93/42/EEC under the supervision of Notified Body Number 1639, SGS Belgium NV, Noorderlaan 87, 2030 Antwerpen, Belgium.

GMDN Code: 66245 (Dental surgical power tool motorized handpiece/set, electric)

EC Certificate Number: KR19/81826314

Responsible for making this declaration is the :

- Manufacturer: Meta Systems Co., Ltd.
- Distributor: Kerr Corporation (1717 W. Collins Ave. Orange, CA 92867 USA)

European Representative is:

- Meta Biomed Europe GmbH, Wiesenstr. 35, 45473 Mülheim an der Ruhr, Germany.
- Tel: +49-208-30991910, Fax: +49-208-30991999

We, the manufacturer, declare and ensure with sole responsibility, that the Medical Device meet the provisions of Council Directive 93/42/EEC (Medical Device Directive) which apply to them.

Person responsible for making this declaration:

Name, Surname : Suk Song Oh
Position/Title : CEO
Place: Seongnam-si **Date:** June 5, 2023

Suk Song Oh
(Company stamp and legal signature)

PART NUMBERS

Part Number	Components
815-1800	Elements Connect Cordless Motor Kit - US
815-1801	Elements Connect Cordless Motor Kit - EU
815-1901-UK	Elements Connect Cordless Motor Kit - UK
815-1901-AU	Elements Connect Cordless Motor Kit - AUS
815-1804	Elements/Apex Connect Power Cord - US
815-1805	Elements/Apex Connect Power Cord - EU
815-1904-UK	Elements/Apex Connect Power Cord - UK
815-1904-AU	Elements/Apex Connect Power Cord - AUS
815-1806	Elements Connect AC/DC Adapter
815-1808	Elements Connect Contra Angle
815-1809	Elements Connect Charging Base
815-1810	Elements Connect Battery Pack
815-1811	Elements Connect Motor Handpiece
815-1900	Elements Connect Motor Handpiece - ROW
815-1906	Elements Connect AC/DC Adapter - ROW
815-1908	Elements Connect Contra Angle – ROW
815-1909	Elements Connect Charging Base – ROW
815-1910	Elements Connect Battery Pack – ROW