

# EC Declaration of Conformity

according to the Medical Devices Directive 93/42/EEC

For the following medical device :

**Product Name :** Electronic Apex Locator

**Brand Name :** Apex Connect

**Classification :** Class IIa by Rule 10 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, EN ISO 17665-1, MEDDEV 2.7.1:2016 (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:** 16355 (Apex locator, endodontic)

**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
815-1802	Apex Connect Kit - US
815-1803	Apex Connect Kit - EU
815-1902-UK	Apex Connect Kit - UK
815-1902-AU	Apex Connect 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
815-1807	Apex Connect AC/DC Adapter
815-1812	Apex Connect Probe Cord
815-1813	Apex Connect Lip Hook
815-1814	Apex Connect File Holder Adapter
815-1815	Apex Connect File Holder A
815-1816	Apex Connect File Holder B
815-1817	Apex Connect Replacement Battery
815-1818	Apex Connect Main Body
815-1907	Apex Connect AC/DC Adapter - ROW
815-1912	Apex Connect Probe Cord - ROW
815-1913	Apex Connect Lip Hook - ROW
815-1914	Apex Connect File Holder Adapter - ROW
815-1915	Apex Connect File Holder A - ROW
815-1916	Apex Connect File Holder B - ROW
815-1917	Apex Connect Replacement Battery - ROW
815-1911	Apex Connect Main Body - ROW