

EC Declaration of Conformity

according to the Medical Devices Directive 93/42/EEC

For the following medical device:

Product Name: Sonic Powered Endo Irrigation

Trade Name: EQ-S

Model Name: EQ-S (Gray) Full Kit, EQ-S (Pink) Full Kit

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 80601-2-60:2010, IEC 60601-1-2:2014, IEC 60601-1-6:2010+A1:2013, IEC 62366-1:2015, IEC 62304:2006+A1:2015, ISO 15223-1:2021, ISO 20417:2021, ISO 7010: 2019, ISO 7405:2018, ISO 10993-1: 2018, EN ISO 13485:2016

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, BE-2030 Antwerpen, Belgium.

GMDN Code: 36047 (Ultrasonic dental scaling/debridement system)

EC Certificate Number : KR19/81826314

Responsible for making this declaration is the :

■ Manufacturer: Meta Systems Co., Ltd.

European Representative is:

■ Meta Biomed Europe GmbH: Schederhofstraße 59, 45145 Essen, 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.

The manufacturer signed the written agreement under MDR by the date of MDD certificate expiry. The transition timelines that apply to the devices covered by this DoC, are shown below: 31st December 2028.

Person responsible for making this declaration:

Name, Surname : Suk Song Oh

Position/Title : CEO

Place: South Korea **Date:** January 1, 2025



(Company stamp and legal signature)

PART NUMBERS

Part Number	Description
026-210	EQ-S (Gray) Full Kit
026-220	EQ-S (Pink) Full Kit
126-230	EQ-S Tip 15/02 [30ea/1set]
126-240	EQ-S Tip 25/02 [30ea/1set]
126-250	EQ-S Tip 35/02 [30ea/1set]
126-070	EQ-S/Protective Sleeve [100ea/1set]