META SYSTEMS CO., LTD.
#1214-18, Sicox tower 12F, 484, Dunchon-daero,
Jungwon-gu, Seongnam-si, Gyeonggi-do, 13229, Korea
TEL. 82 31 731 7377 / FAX. 82 31 731 1888

EC Declaration of Conformity

according to the Medical Devices Directive 93/42/EEC

For the following medical device :

Product Name :	Sonic Powered Endo Irrigation
Brand Name :	EQ-S
Model Name :	026-210, 026-220
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, 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, 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, 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, Wiesenstr. 35, 45473 Mulheim 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 : **PRESIDENT**

Place: **Seongnam-si** **Date:** **April. 04, 2022**

Suk Song Oh

(Company stamp and legal signature)