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 :	Hand plugger
Brand Name :	EQ Condenser
Model Name :	027-110, 027-120, 027-130, 027-240
Classification :	Class I by Rule 6 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:

ISO 14971:2019, EN ISO 15223-1:2016, EN 1041:2008, ISO 7010:2019, EN ISO 10993-1:2018, EN ISO 7405:2018, ISO 10993-5: 2009, EN ISO 10993-10: 2013, EN ISO 13485:2016, ISO 11737-1:2018, ISO 11737-2:2019, ISO 17664:2017, ISO 17665-1: 2006, MEDDEV 2.7.1:2016 (Rev.4)

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:** **November 16, 2020**

Suk Song Oh

(Company stamp and legal signature)