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 :	Endodontic Obturation System
Brand Name :	EQ-V
Model Name :	EQ-V PACK KIT, EQ-V FULL GP, EQ-V FILL GP
Classification :	Class Ⅱa by Rule 11 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 80601-2-60:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2010+AMD1:2013, IEC 62366:2007+AMD1:2014, IEC 62304:2006+AMD1:2015, IEC 62133:2012, ISO 15223-1:2021, ISO 20417:2021, ISO 7010:2019, ISO 7405:2018, ISO 10993-1: 2018, EN ISO 13485:2016, ANSI/AAMI ST79: 2010, ISO 17664-1:2021, 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: 45247 (Endodontic obturation 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:** **Sep 11, 2023**

Suk Song Oh

(Company stamp and legal signature)

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No.	Part No.	Description (Part Name)
1	EQV022	EQ-V PACK KIT
2	EQV026	EQ-V FULL GP
3	EQV027	EQ-V FILL GP
4	EQV-F10	EQ-V FILL
5	EQV-P10	EQ-V PACK
6	EQV-C21	Dual Charger
7	EQV-C22	Single Charger
8	EQV-C30	Battery
9	EQV-F35	Fill needle 23G (6 pcs)
10	EQV-F36	Fill needle 25G (6 pcs)
11	EQV-F32	Fill needle 23G/25G (6 pcs)
12	EQV-P34	Pack tip (40/03)
13	EQV-P35	Pack tip (50/04)
14	EQV-P36	Pack tip (60/05)
15	EQV-P37	Pack tip (60/05L)
16	EQV-P38	Pack tip (50/04, 60/05)
17	EQV-P33	Pack tip (40/03, 50/04)
18	EQV-P32	Pack tip (40/03, 50/04, 60/05, 60/05L)
19	WS-010+WS-002	Power cord (EU)
20	4451ECAD01	AC/DC Adapter