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

DECLARATION OF CONFORMITY

Model : EQ-V

Manufacturer:

Meta Systems Co., Ltd.
#1214-18, Sicox tower 12F, 484, Dunchon-daero, Jungwon-gu,
Seongnam-si, Gyeonggi-do, 13229, Korea

EC Representative:

Meta Biomed Europe GmbH
Wiesenstr. 35, 45473
Mülheim an der Ruhr, Germany
Tel: +49 208 30991910, Fax: +49 208 30991999

Certificate Authority:

SGS Belgium NV
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

Risk Classification:

Class Ⅱa, by Rule 11 of Annex Ⅸ, MDD 93/42/EEC

Has been classified as Class IIa (Annex IX Rule 11) and is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC is subject to the procedures set out in Annex II of Directive 93/42/EEC under the supervision of Notified SGS (NB. No. ; 1639)
SGS House Noorderlaan 87 2030 Antwerp Belgium

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Medical Device(s): EQ-V

Product Number	Product Description
EQV022	EQ-V PACK KIT
EQV026	EQ-V FULL GP
EQV027	EQ-V FILL GP
EQV-F10	EQ-V FILL (Handpiece)
EQV-P10	EQ-V PACK (Handpiece)
EQV-C22	Single Charger
EQV-C21	Dual Charger
4451ECAD01	AC/DC Adapter
WS-010+WS-002	Power cord (EU)
EQV-C30	Li-ion Battery
EQV-P21	Pack tip (40/03)
EQV-P22	Pack tip (50/04)
EQV-P23	Pack tip (60/05)
EQV-P24	Pack tip (60/05L)
EQV-P25	Pack tip (50/04, 60/05)
EQV-F35	Fill needle (23G, 6ea)
EQV-F36	Fill needle (25G, 6ea)
M021-ACC01	STP (Silicone Thermal Protector)
EQ037	Brush
EQ035	Multi tool
EQV-F13	Plunger
EQV-F24	Plunger seal (2ea)
EQV-F25	Seal driver

Standards Applied:

EN ISO 14971:2012	Medical devices Application of risk management to medical devices
IEC 60601-1:2005 +A1:2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical electrical equipment – Part1-2: General requirements for safety and essential performance – Collateral standard: Electromagnetic compatibility –Requirements and tests
EN 60601-1-6: 2010	Medical electrical equipment – Part 1-6: General requirements for safety and essential performance – Collateral standard: Usability
EN 62366: 2008	Medical devices – Application of usability engineering to medical devices
EN 62304: 2006	Medical device software – Software life cycle processes
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels,

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	labeling and information to be supplied – Part 1: General requirements
EN 1041: 2008	Information supplied by the manufacturer with medical devices
ISO 7010: 2011	Graphical symbols – Safety colors and safety signs – Registered safety signs
EN ISO 10993-1: 2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 13485:2016	Quality management systems - Requirements for regulatory purposes
ISO 11737-1: 2006	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
ISO 11737-2: 2009	Sterilization of medical devices – Microbiological method – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterility performed in the definition, validation and maintenance of a sterilization process

This declaration of conformity is valid from Jan 30, 2020.

Suk Song Oh

Authorized Signature

S. S. Oh, CEO — Name, Title

01 / 30 / 2020 — Date