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 : elementsIC

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

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. ; 0120)
Unit 202B, Worle Parkway, Weston-Super-Mare, BS22 6WA United Kingdom

Medical Device(s): elementsIC

Product Number	Product Description
973-0600-TYPEB	elementsIC Obturation System (North America)
973-0600-TYPEG	elementsIC Obturation System (UK)
973-0600-TYPEF	elementsIC Obturation System (EU)
973-0600-TYPEI	elementsIC Obturation System (Aus)
973-0600-TYPEN	elementsIC Obturation System (Brazil)
973-0602-TYPEB	Downpack Unit, elementsIC (North America)
973-0602-TYPEG	Downpack Unit, elementsIC (UK)
973-0602-TYPEF	Downpack Unit, elementsIC (EU)
973-0602-TYPEI	Downpack Unit, elementsIC (Aus)
973-0602-TYPEN	Downpack Unit, elementsIC (Brazil)

973-0604-TYPEB	Backfill Unit, elementsIC (North America)
973-0604-TYPEG	Backfill Unit, elementsIC (UK)
973-0604-TYPEF	Backfill Unit, elementsIC (EU)
973-0604-TYPEI	Backfill Unit, elementsIC (Aus)
973-0604-TYPEN	Backfill Unit, elementsIC (Brazil)
973-0610	Dual Charger, elementsIC
973-0612	Single Charger, elementsIC
973-0615	Transformer, elementsIC
973-0616 -TypeB	Power Cord, Type B (North America)
973-0616 -TypeF	Power Cord, Type F (EU)
973-0616 -TypeG	Power Cord, Type G (UK)
973-0616 -TypeI	Power Cord, Type I (Aus)
973-0616 -TypeN	Power Cord, Type N (Brazil)
973-0620	Battery, elementsIC

Risk Classification:

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

Certificate Authority:

The supervision of Notified Body Number 0120,

SGS United Kingdom Limited, Unit 202B, Worle Parkway, Weston-Super-Mare, BS22 6WA United Kingdom

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, labeling and information to be supplied – Part 1: General requirements

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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 May 21, 2019

Suk Song Oh

Authorized Signature

S. S. Oh, CEO — 5 / 21 / 2019

Name, Title — Date