EC Declaration of Conformity

Manufacturer's name	**ALPINION MEDICAL SYSTEMS Co., Ltd.**
SRN Code	KR-MF-000012961
Address	5FL, I Dong, 77, Heungan-daero 81 beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, Republic of Korea +82 2 3282 0900
European representative	**Alpinion Medical Deutschland GmbH**
SRN Code	DE-AR-000008603
Address	Lilienthalstrasse 17a 85399 Hallbergmoos Germany
Phone	+49 811 99 82 86 0

Declares that the product:

Device Category	Ultrasound Imaging System
Model Name	**X-CUBE 90 and X-CUBE 70** - With following probes/ transducers: SC1-7H, L4-18H, L3-15H, IO7-18, C5-8NT, MP1-5X, SVC1-8H, EC2-11H, SC2-8H, SP3-8T, EV3-10X, EC3-10X, VE3-10H, CW2.0, CW5.0, L3-8H, L3-12X, SC2-9H, CW8.0, TEE3-7, SP4-12, L10-25H, SL3-19H, P1-5CT, EV2-11H, SL3-19X, SC2-11H
GMDN Code	40761(Ultrasound Imaging system), 40768(Hand-held transducers), 40771(Vaginal transducers),
Basic UDI-DI Code	08800013570008C
Classification	Class IIa by Rule 10 of Annex VIII, Medical Device Regulation (EU) 2017/745 of the European parliament
Conformity Assessment Route	Annex IX excluding Chapter II of Medical Device Regulation (EU) 2017/745 of the European parliament

Responsibility: This EU declaration of conformity is issued under the sole responsibility of manufacturer.

Applicable standard: See Attachment

We hereby declare that the product is in conformity with the GSPR (General safety and performance Requirements) and provisions of Medical Device Regulation (EU) 2017/745 of the European parliament, is subject to a conformity assessment as specified in Chapter I and III of Annex IX of Medical Device Regulation (EU) 2017/745 of the European parliament, under the supervision of Notified Body, DNV Product Assurance AS (NB No.:2460), Veritasveien 3, N-1363 Høvik, Norway.

※The EU declaration of conformity must be translated into the language or languages required by the Member State in which the product is placed or made available on the market. Union harmonization legislation does not necessarily specify who has the obligation to translate. Logically, this should be the manufacturer or another economic operator making the product available.

Boyeon, Cho

PRRC & QMR

CE 2460

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2022.05.31

Attachment

Standard	Description
EU MDR 2017/745	Medical Device Regulation (EU) 2017/745 of the European parliament,
EN ISO 13485:2016 (ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 60601-1:2006+A2:2014 (IEC 60601-1:2005/AMD1:2012/COR1:2014)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015 (IEC 60601-1-2:2014)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010+A1:2015 (IEC 60601-1-6:2010/AMD1:2013)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-2-37:2008+A11:2011+A1:2015 (IEC 60601-2-37:2007/AMD1:2015)	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
EN ISO 10993-1:2009 (ISO 10993-1:2009)	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
EN ISO 10993-10:2013 (ISO 10993-10:2010)	Biological evaluation of medical devices. Tests for irritation and skin sensitization
EN ISO 10993-5:2009 (ISO 10993-5:2009)	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
EN 61000-3-2:2014 (IEC 61000-3-2:2018)	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤16 A per phase)
EN 61000-3-3:2013 (IEC 61000-3-3:2013)	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16 A per phase and not subject to conditional connection
EN 61000-4-11:2004 (IEC 61000-4-11:2004)	Amendment 1 - Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests
EN 61000-4-2:2009 (IEC 61000-4-2:2008)	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
EN 61000-4-3:2006+A1:2008+A2:2010 (IEC 61000-4-3:2006/AMD2:2010)	Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
EN 61000-4-4:2012 (IEC 61000-4-4:2012)	Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test
EN 61000-4-5:2014 (IEC 61000-4-5:2014)	Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test
EN 61000-4-6:2014 (IEC 61000-4-6:2013)	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields
EN 61000-4-8:2010 (IEC 61000-4-8:2009)	Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test
EN 55011:2016+A1:2017 (CISPR 11:2015/AMD1:2016)	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement
EN 55032:2015 (CISPR 32:2015)	Electromagnetic compatibility of multimedia equipment - Emission requirements
EN 62304:2006+A1:2015 (IEC 62304:2006/AMD1:2015)	Medical device software – Software life cycle processes
EN 62366-1:2015 (IEC 62366-1:2015)	Medical devices - Application of Usability engineering to medical devices
EN ISO 14971:2019 (ISO 14971:2019)	Medical Device – Application of Risk Management to medical devices
EN ISO 15223-1:2021 (ISO 15223-1:2021)	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer with medical devices
MEDDEV 2.12/2 Rev.2	Post market clinical follow up studies
MEDDEV 2.7.1 Rev.4	Clinical evaluation

MEDDEV 2.12-1 Rev.8	Medical Devices Vigilance system
MDCG 2018-1_Rev.4	BASIC UDI-DI and Changes to UDI_DI
MDCG 2019-11_Rev.0	Qualification and Classification of SW
MDCG 2019-16	Cybersecurity for MD
MDCG 2020-5	Clinical Evaluation-Equivalence
MDCG 2020-6	Clinical Evidence needed for medical devices previously CE marked
MDCG 2020-7	PMCF Plan Template
MDCG 2020-8	PMCF Evaluation report Template