EC Declaration of Conformity

Manufacturer's name	**ALPINION Medical Systems Co., Ltd.**
Address	5FL, I Dong, 77, Heungan-daero 81 beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, Republic of Korea
European representative	**Alpinion Medical Deutschland GmbH**
Address	Lilienthalstrasse 17a 85399 Hallbergmoos Germany
Phone	+49 811 99 82 86 0

Declares that the product:

Device Category	Ultrasound Imaging System
Classification	Class IIa by Rule 10 of Annex IX, MDD 93/42/EEC as amended by Directive 2007/47/EC
Conformity Assessment Route:	Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended
Responsibility	The manufacturer is exclusively responsible for the declaration of conformity

Device Category	Model	GMDN code
MD 1202 Ultrasound Imaging System	E-CUBE 5, E-CUBE 5 W, E-CUBE 7, E-CUBE 8, E-CUBE 8 LE, E-CUBE 8 Diamond, E-CUBE 9, E-CUBE 15, E-CUBE 12, E-CUBE inno, E-CUBE i7, E-CUBE 11, minisono C1-6, minisono L3-12, X-CUBE 90	40761
MD 1202 Hand-held transducers	C1-6, C1-6i, C1-6T, C1-6CT, C5-8, C5-8N, C5-8NT, SC1-6, SC1-6H, SC1-4H, SC1-4HS, SC1-4M, SC1-7H, SC2-8H, SC2-9H, SL3-19H, L3-8, L3-8H, L3-8i, L3-12, L3-12H, L3-12H^{WD}, L3-12i, L3-12X, L3-12T, L8-17, L8-17i, L8-17X, L8-17H, L3-15H, L4-18H, L10-25H, SP1-5, SP1-5T, SP1-5i, SP1-5X, P1-5CT, SP3-8, SP3-8T, SPN1-5X, MP1-5X, MP3-8, SP4-12 VC1-6, VC1-6T, SVC1-6, SVC1-6H, SVC1-8H, IO3-12, IO8-17, IO8-17T, IO7-18, CW2.0, CW5.0, CW8.0	40768
MD 1202 Vaginal transducers	E3-10, E3-10H, EN3-10, EV3-10, EC3-10, EV3-10T, EC3-10T, EV3-10H, EC3-10H, EV3-10X, EC3-10X, VE3-10H, EC2-11H, EV2-11H	40771
MD 1202 Oesophageal ultrasound imaging system transducer, reusable	TEE3-7	37891

Applicable standard: See Attachment

We hereby declare that the product is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by Directive 2007/47/EC, is subjects to the procedures set out in Annex II of Directive 93/42/EEC as amended by Directive 2007/47/EC, with exemption of section 4 under the supervision of Notified Body, DNV GL PRESAFE 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 harmonisation 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.

Digitally signed by Botnaru Andrei
Date: 2022.12.23 15:01:36 EET
Reason: MoldSign Signature
Location: Moldova

Boyeon Cho

Quality Management Representative

Date: 2019-12-27

Attachment

Standard No.	Title of Document
MDD 93/42/EEC	European Medical Devices Directive 93/42/EEC including amendments by 2007/47/EC
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 ISO 13485:2016 (ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012 (ISO 14971:2019)	Medical Device – Application of Risk Management to medical devices
EN ISO 15223-1:2016 (ISO 15223-1:2016)	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
EN 55011:2016+A1:2017 (CISPR11:2015/AMD1:2016+ AMD2:2019)	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement
EN 55032:2015 (CISPR 32:2015+AMD1:2019)	Electromagnetic compatibility of multimedia equipment - Emission requirements
EN 60601-1:2006+A1:2013 (IEC 60601-1:2005/AMD1: 2012)	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

Standard No.	Title of Document
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 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
MEDDEV 2.12/2 Rev.2	Post market clinical follow up studies
MEDDEV 2.7.1 Rev.4	Clinical evaluation