EC Declaration of Conformity

Manufacturer's name	**ALPINION MEDICAL SYSTEMS Co., Ltd.**
SRN Code	KR-MF-000012961
Address	4F, 15, Magokjungang 14-ro, Gangseo-gu, Seoul, 07789, Republic of Korea Tel. +82.2.3777.8500 (KOR), +82.2.3777.8600 (Overseas)
European representative	**Alpinion Medical Deutschland GmbH**
MDR Certificate No.	10000480396-PA-NoMA-KOR
SRN Code	DE-AR-000008603
Address	Lilienthalstrasse 17a 85399 Hallbergmoos Germany +49 811 99 82 86 0

Declares that the product:

Device Category	Ultrasound Imaging System
Model Name	**X-CUBE 90 and X-CUBE 70** (0880001357000QZ) - 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
	X-CUBE 60 (0880001357000QZ) - With following probes/ transducers: SC1-7H, SC2-11H, SVC1-8H, P1-5CT, L3-15H, L3-8H, L3-12X, EC2-11H, EV2-11H, VE3-10H, CW2.0, CW5.0, CW8.0, SL3-19X, L10-25H, C1-6C, C1-6CT
	X-CUBE 50 (0880001357000QZ) - With following probes/ transducers: SC2-11H, C1-7GT, SVC1-8H, P1-5CT, L3-15H, L3-8H, L3-12HWD, EC3-10T, EV3-10T, VE3-10H, CW2.0, CW5.0, CW8.0, C1-6CT
	X-CUBE i8 and X-CUBE i9 (0880001357200RB) - With following probes/ transducers: L3-8H, L3-12T, L3-12HWD, SL3-19H, L10-25H, IO7-18, SC1-7H, C1-6C, SC2-9H, MP1-5X, P1-5CT, EV3-10T, EC3-10T, EC2-11H, EV2-11H, CW2.0, CW5.0, TEE3-7
	E-CUBE 15 (0880001357100R6) - With following probes/ transducers: SC1-4H, SC1-6H, SC1-4HS, SC1-4M, C5-8, C5-8N, SVC1-6, SVC1-6H, SP1-5X, SP3-8, SPN1-5X, MP1-5X, L3-8, L3-12H, L3-12X, L8-17X, IO3-12, IO8-17, L3-8H, E3-10H, EV3-10H, EC3-10H, EV3-10X, EC3-10X, VE3-10H, VE3-10HN, CW2.0, CW5.0, TEE3-7
	E-CUBE 12 (0880001357100R6) - With following probes/ transducers: SC1-6H, SC1-4HS, C1-6CT, SVC1-6H, C5-8NT, P1-5CT, SP3-8T, L3-12H, L3-12HWD, L8-17H, L3-8H, L3-12X, L8-17X, IO8-17T, IO3-12, EV3-10H, EC3-10H, EV3-10X, EC3-10X, VE3-10H, CW2.0, CW5.0
	E-CUBE 8, E-CUBE 8 LE, E-CUBE 8 Diamond (0880001357100R6) - With following probes/ transducers: SC1-6H, SC1-4H, SC1-4HS, C1-6CT, C5-8NT, VC1-6T, P1-5CT, SP3-8T, L3-12T, L3-12H, L3-12HWD, IO8-17T, IO3-12, L8-17H, EC3-10T, EV3-10T, VE3-10H, CW2.0, CW5.0
	E-CUBE 5, E-CUBE 5W (0880001357100R6) - With following probes/ transducers: C1-6T, C5-8NT, L3-12T, EV3-10T, EC3-10T

	E-CUBE i7 (0880001357300RG) - With following probes/ transducers: SP1-5T, SP3-8T, C1-6T, C5-8NT, VC1-6T, L3-12T, IO8-17T, L3-8H, L3-12HWD, L8-17H, IO3-12, EC3-10T, EV3-10T, CW2.0, CW5.0
GMDN Code	40761(Ultrasound Imaging system), 40768(Hand-held transducers), 40771(Vaginal transducers)
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 Veritasveien 1, 1363 Høvik, Norway. We hereby declare that the product does not contain hazardous substances listed Directive 2011/65/EU of the European Parliament and the amendment 2015/863/EU of 31 March 2015 on the restriction of the use of certain Hazardous substances in electrical and electronic equipment.

※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.

SangWoong, Lee

PRRC & QMR

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