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EU Quality Management System Certificate

Certificate no.:
10000480396-PA-NoMA-KOR

Initial certification date:
31 May 2022

Valid Until:
31 May 2027

This is to certify that the quality system of

ALPINION MEDICAL SYSTEMS Co., Ltd.

4F, 15, Magokjungang 14-ro, Gangseo-gu, Seoul, 07789, Republic of Korea
SRN: KR-MF-000012961

For design, production, and final product inspection/testing of:

Diagnostic Ultrasound Probe and Diagnostic Ultrasound Imaging System.

Has been assessed and found to comply with respect to:

The conformity assessment procedure described in Annex IX, (Chapter I & III) of Regulation (EU) 2017/745 on Medical Devices

Place and date:
Høvik, 09 December 2022

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Hazem Tinawi
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

Jurisdiction

Application of Regulation 2017/745 on medical devices, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Report No.	Issue Date
0.0	Original Certificate	2573052	31 May 2022
1.0	Scope extension – Addition of new models (X-CUBE 50, X-CUBE 60) and new transducer in bold – List up applicable Transducer	2728785	03 November 2022
2.0	**MDR SE for site relocation (Single site > Multi-site).**	2814063	09 December 2022

Products covered by this Certificate:

Product Description (and intended purpose for class IIb)	Product Name	Class*
Diagnostic Ultrasound Imaging System	X-CUBE 90, X-CUBE70 X-CUBE 50, X-CUBE 60	IIa
	minisono C1-6, minisono L3-12	
	E-CUBE 15, E-CUBE 12, E-CUBE 8, E-CUBE 8 LE, E-CUBE 8 Diamond, E-CUBE 5, E-CUBE 5 W	
	E-CUBE i7	
	X-CUBE i9, X-CUBE i8	
Diagnostic Ultrasound Probe (Applicable transducer to the above imaging system)	C1-6C, C1-6CT, C1-6T, C1-7GT, C5-8, C5-8N, C5-8NT, CW2.0, CW5.0, CW8.0, E3-10H, EC2-11H, EC3-10H, EC3-10T, EC3-10X, EV2-11H, EV3-10H, EV3-10T, EV3-10X, IO3-12, IO7-18, IO8-17, IO8-17T, L10-25H, L3-12H, L3-12HWD, L3-12T, L3-12X, L3-15H, L3-8, L3-8H, L4-18H, L8-17H, L8-17X, MP1-5X, P1-5CT, SC1-4H, SC1-4HS, SC1-4M, SC1-6H, SC1-7H, SC2-11H, SC2-8H, SC2-9H, SL3-19H, SL3-19X, SP1-5T, SP1-5X, SP3-8, SP3-8T, SP4-12, SPN1-5X, SVC1-6, SVC1-6H, SVC1-8H, TEE3-7, VC1-6T, VE3-10H, VE3-10HN	IIa

* Class III and class IIb devices referred to in the second subparagraph of Article 52(4): Technical documentation assessment is covered by a separate EU Technical Documentation Assessment Certificate No.: NA

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
ALPINION MEDICAL SYSTEMS Co., Ltd.	4F, 15, Magokjungang 14-ro, Gangseo-gu, Seoul, 07789, Republic of Korea
ALPINION MEDICAL SYSTEMS Co., Ltd. (Factory)	4F, 16, Simin-daero 327beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, 14055, Republic of Korea

EU Representative
ALPINION MEDICAL Deutschland GmbH Lilienthalstrasse 17a 85399 Hallbergmoos Germany

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.
- For the class III devices covered this certificate is dependent on the continued validity of the EU Technical Documentation Assessment Certificate, covering the devices.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window

Specific conditions - Class I devices, Systems and Procedure Packs:

- For class I device being placed on the market in a sterile condition, Class I devices with a measurement function and class I devices being reusable surgical instruments covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 52(7) of the regulation.
- For system and procedure packs being placed on the market in a sterile condition, covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 22(3) of the regulation.
- For Custom Made Class III implantable device the certification only relates to the Quality management system. Technical documentation assessment and issuance of EU Technical Documentation Assessment Certificate does not apply.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EU declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.