

# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:  
9809-2017-AQ-KOR-NA-PS

Initial certification date:  
04 October 2013

Valid:  
27 December 2022 – 26 December 2025

This is to certify that the management system of  
**ALPINION Medical Systems Co., Ltd.**  
4F, 15, Magokjungang 14-ro, Gangseo-gu, Seoul, 07789, Republic of Korea  
and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:  
**ISO 13485:2016 / EN ISO 13485:2016**

This certificate is valid for the following scope:

**Design, Development, Manufacture, sales, distribution and servicing of Diagnostic  
Ultrasound Probe, Diagnostic Ultrasound Imaging System and High Intensity Focused  
Ultrasound**

Place and date:  
Høvik, 27 December 2022



For the issuing office:  
**DNV Product Assurance AS**  
Veritasveien 1, 1363 Høvik, Norway

*Cecilie Gudesen Torp*

**Cecilie Gudesen Torp**  
Management Representative

## Appendix to Certificate

### ALPINION Medical Systems Co., Ltd.

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
ALPINION Medical Systems Co., Ltd.	4F, 15, Magokjungang 14-ro, Gangseo-gu, Seoul, 07789, Republic of Korea	Design, Development, sales, distribution and servicing of Diagnostic Ultrasound Probe, Diagnostic Ultrasound Imaging System and High Intensity Focused Ultrasound. Manufacture of Diagnostic Imaging System.
ALPINION Medical Systems Co., Ltd.(Factory)	4F, 16, Simin-daero 327beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, 14055, Republic of Korea	Manufacture of Diagnostic Ultrasound Imaging System, Diagnostic Ultrasound Probe and High Intensity Focused Ultrasound.