

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
9809-2017-AQ-KOR-NA-PS Rev. 3.0

Initial certification date:
4 October 2013

Valid:
2 November 2021– 1 November 2024

This is to certify that the management system of

ALPINION Medical Systems Co., Ltd.

5FL, I Dong, 77, Heungan-daero 81 beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, Republic of Korea

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, production, sales, distribution and servicing of Ultrasound Imaging System and High Intensity Focused Ultrasound.

Place and date:
Høvik, 02 September 2021



For the issuing office:
DNV Product Assurance AS
Veritasveien 3, 1363 Høvik, Norway

Hazem Tinawi
Technical Reviewer