

Management System Certificate

Certificate No.:
9809-2017-AQ-KOR-NA-PS Rev. 1.0

Project No.:
PRJC-558666-2017-MSL-KOR

Initial Certification Date:
4 October 2013

Valid Until:
1 November 2021

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

With sites as listed overleaf.

Complies with the requirements of:

ISO 13485:2016/NS-EN ISO 13485:2016

The Certificate is valid for the following scope:

Design, development, production, installation, sales, distribution and servicing of Ultrasound Imaging System and High Intensity Focused Ultrasound

Place and Date:
Høvik, 7 November 2018



For:
DNV GL PRESAFE AS

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The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

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Site Name	Address	Site Scope
Headquarter & Factory 1	5FL, I Dong, 77, Heungan-daero 81 beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, Republic of Korea	Design, development, production, sales, distribution and servicing of Ultrasound Imaging System
Factory 2	Room 610, ACE HIGH-END Tower 1st, 5, Digital-ro 26-gil, Guro-gu, Seoul, Republic of Korea	Design, development, production, sales, distribution and servicing of High Intensity Focused Ultrasound

End of Certificate