

Certificate

Certificate No.: MD 2004702-1-1

Manufacturer: **GE Ultrasound Korea, Ltd.**
9, Sunhwan-ro,
214beon-gil, Jungwon-gu,
Seongnam-si, Gyeonggi-do, 13204
Republic of Korea

REPs Facility ID: F004681

Certification criteria: ISO 13485:2016

Australia Therapeutic Goods (Medical Devices) Regulations, 2002,
Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance
Procedure

Brazil RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021,
RDC ANVISA n. 67/2009

Canada Medical Devices Regulations – Part 1 – SOR 98/282

Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD
Act

United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 –
Subparts A to D

Scope: ■ Design and Development, Manufacture and Distribution of
Ultrasound Diagnostic Devices and Systems.

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 234215065-12

Issue Date: 2024-09-09

Effective Date: 2024-10-19

Expiry Date: 2027-10-18



Certification officer: Aihe Huang
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on <https://www.certipedia.com>
or calling 1-888-743-4652.