

Certificate

Certificate No.: MD 2214790-1-2

Manufacturer: **TeraRecon Inc.**
4309 Emperor Boulevard Suite 310
Durham NC 27703
USA

REPs Facility ID: F004260

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

Japan PMD Act (as applicable)

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

Scope: Design and Development, Manufacture, Installation, Distribution and
Maintenance of image processing, archiving and communication
software for area of radiologists and clinicians aiding patient
diagnosis.

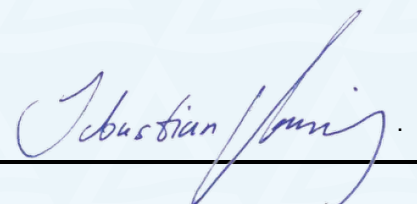
TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject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

Project No.: 234219889-12

Issue Date: 2024-11-27

Effective Date: 2024-11-27

Expiry Date: 2027-11-10



Certification officer: Sebastian Mniszek
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.

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The scope of certification also covers the following sites:

No.	Location	Scope
/01	TeraRecon Inc. 4309 Emperor Boulevard Suite 310 Durham NC 27703 USA	Activities Related to Design and Development, Manufacture, Distribution, Installation, Servicing and Administration Facility ID# F004260
/02	TeraRecon, Inc. STE 240 39141 Civic Center Drive Fremont CA 94538 USA	Activities Related to Design and Development, Manufacture, Distribution, Installation, Servicing and Administration Facility ID# F005259

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