

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 2214790-1

Certificate Holder: TeraRecon Inc.
4309 Emperor Boulevard Suite 310
Durham NC 27703
USA

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.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 234219889-11

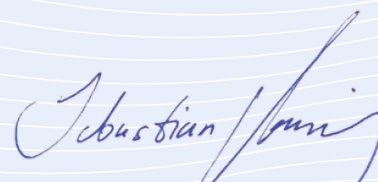
Effective date: 2025-01-20

Expiry date: 2028-01-19

Issue date: 2024-11-27

Replaces certificate SX 2214790-1 issued 2024-08-12

This certificate can be validated on <https://www.certipedia.com>



Sebastian Mniszek
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

© TÜV, TÜV and TÜV are registered trademarks. Utilisation and application requires prior approval.

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 2214790-1

Certificate Holder: TeraRecon Inc.
4309 Emperor Boulevard Suite 310
Durham NC 27703
USA

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o TeraRecon Inc. 4309 Emperor Boulevard Suite 310 Durham NC 27703 USA	Activities Related to Design and Development, Manufacture, Distribution, Installation, Servicing and Administration.
/02	c/o TeraRecon, Inc. STE 240 39141 Civic Center Drive Fremont CA 94538 USA	Activities Related to Design and Development, Manufacture, Distribution, Installation, Servicing and Administration
/03	c/o TeraRecon GmbH Walther-von-Cronberg-Platz 16 60594 Frankfurt Germany	Activities Related to Distribution, Installation, Servicing and Administration.

This certificate can be validated on <https://www.certipedia.com>