

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## TERATECH Corporation

Main Site: 77-79 Terrace Hall Avenue, Burlington, Massachusetts 01803  
(DUNS #836416321)

has been registered by Intertek, an MDSAP recognized auditing organization,  
as conforming to the requirements of:

### ISO 13485:2016

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

**Brazil:** Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

**Canada:** Medical Devices Regulations – Part 1- SOR 98/282

**United States:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

### The management system is applicable to:

The design, manufacturing and service of medical diagnostic ultrasound imaging equipment.

**Certificate Number:**

0076337-00

**Initial Certification Date:**

2018-06-01

**Certification Effective Date:**

2018-06-01

**Certification Expiry Date:**

2021-05-31



**Calin Moldovean**

President, Business Assurance

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