EC CERTIFICATION

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

TERATECH Corporation

Main Site: 77-79 Terrace Hall Avenue Burlington, Massachusetts 01803, USA

Product Category:

- Portable Medical Ultrasound Imaging Equipment

For further identification of the products covered, see the MDD product list/product schedule.

Certificate Number:
41313831-02

Initial Certification Date:
22 March 2001

Certificate Valid from:
23 March 2021

Certificate Expiry Date:
26 May 2024

SWEDAC ACKREDITERING
Accred. no. 1003
Certification of Management Systems
ISO/IEC 17021-1

Bob Andersson
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

23 February 2021
Signed Date

Intertek Semko AB
Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00
medtechsweden@intertek.com

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.

MDD – Product List

Products included in the Certificate No: 41313831-02
Issued to: **TERATECH Corporation**
77-79 Terrace Hall Avenue
Burlington, Massachusetts 01803
USA

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Portable Medical Ultrasound Imaging Equipment					
Ultrasound Imaging Equipment					
	Terason uSmart3200T	IIa	No	-	Apr 29, 2013
	Terason uSmart3200T Plus	IIa	No	40761	Mar 20, 2019
	Terason uSmart3300	IIa	No	-	Mar 14, 2014
Accessories					
Transducers					
	12L5-A, 8EC4A, 4V2-A, 8BP4, PDOF	IIa	No	-	*
	10BP4	IIa	No	-	Mar 25, 2020
	16HL7, 15L4	IIa	No	-	Apr 26, 2011
	XY Bi-plane	IIa	No	-	Mar 25, 2020
	5C2A, 8L2	IIa	No	-	Apr 20, 2012
	8V3A	IIa	No	-	Mar 28, 2014
	9MC3, 8TE3	IIa	No	-	Feb 6, 2015
	10EC4	IIa	No		Mar 20, 2019
	15L4A	IIa	No	114121	July 12, 2016
	16L5	IIa	No	-	Feb 28, 2017
	15WL4	IIa	No		Feb 28, 2017
	15XL4	IIa	No	-	Mar 25, 2020
	5V1A	IIa	No		Feb 28, 2017
ECG Trigger					
	ECG Trigger	IIa	No	-	*

* Product added before June 10, 2010.

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Telephone +46 8 750 00 00, Fax +46 8 750 60 30, www.sweden.intertek-etlsemko.com
Registered in Sweden: No SE556024059901, Registered office: As address

MDD – Product List

Sign Date: 23 February 2021
Valid Date: 23 March 2021

Intertek Semko AB
Notified Body MDD

Bob Andersson
Certification Authority MDD

This product list is only valid together with the referenced, valid EC certificate.

The GMDN codes are assigned by the manufacturer and are only provided for convenience.

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Registered in Sweden: No SE556024059901, Registered office: As address

MDD – Decision Report

Certificate No: 41313831-02
Date: 23 February 2021
Handled by: Caroline Åman
E-mail: medtechsweden@intertek.com

TERATECH Corporation
Attn: Ben Chiampa
77-79 Terrace Hall Avenue
Burlington, Massachusetts 01803
USA

Purpose	Assessment to issue a new certificate due to five year extension according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II.
Activity	Certification audit was performed 27 October 2021 in Burlington by Mark Ciceran. The technical file was reviewed by Joan Medley and Britt-Marie Gustavsson at Intertek's office.
Scope of assessment	- Portable Medical Ultrasound Imaging Equipment, Class IIa.
Result	0 non conformities were noted during the audit.
Certificate Valid from	23 March 2021
Conclusions/Decisions	Referring to the above a Certificate of Conformance with the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II will be issued. The Certificate is valid for products specified in the "MDD – Product List".
Follow-up assessments	Follow-up assessments are going to be performed once a year.
Appeals	Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Semko AB, PO-Box 1103, SE-164 22 Kista, Sweden.
Others	Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Semko has the right to review this documentation.

Intertek Semko AB
Notified Body MDD

Bob Andersson
Certification Authority MDD