

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Hamilton Thorne, Inc.

(FIN F005310)

Main Site: 100 Cummings Center, Suite 465E

Beverly, Massachusetts, 01915, United States

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)

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

The management system is applicable to:

Design and Development, Manufacture, Distribution, Installation and Service of Integrated Visual Optical Systems for Analyzing Static and Moving Cells, and Assisted Reproduction Laser Systems for Cell and Embryo Microsurgery and Treatment.

Certificate Number:

0112652

Initial Certification Date:

2021-05-17

Date of Certification Decision:

2021-05-17

Certification Effective Date:

2021-05-17

Certification Expiry Date:

2024-05-16



Intertek

Calin Moldovean

President, Business Assurance

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