

# 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:** RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009

**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 (as applicable)

**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

**Revision Level:** 01

**Initial Certification Date:**

2021-05-17

**Certification Effective Date:**

2024-05-16

**Certification Expiry Date:**

2027-05-16



A handwritten signature in black ink, appearing to read "Calin Moldoveanu", is written over a horizontal line.

**Calin Moldoveanu**

President, Business Assurance

Intertek Testing Services NA, Inc.  
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Kentwood, MI, USA, 49512

