

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Mui Scientific, Division of H & A Mui Enterprises Inc.

(FIN F003890)

Main Site: 145 Traders Boulevard East, Unit #34

Mississauga, Ontario L4Z 3L3 Canada

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

The management system is applicable to:

Design, manufacture and distribution of non-sterile catheters for gastrointestinal motility diagnosis, barostat bag pump with non-sterile catheters for the diagnosis of anorectal disorders, introducers to aid catheter intubation, as well as endoscopes.

Service of manometric pumps.

Certificate Number:

0090801

Revision Level: 05

Initial Certification Date:

2019-05-17

Certification Effective Date:

2025-05-16

Certification Expiry Date:

2028-05-16



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A handwritten signature in black ink.

Rathin Grover

President, Business Assurance

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