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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: 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, manufacture and distribution of manometric pumps with 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.

Certificate Number:
0090801-3

Initial Certification Date:
2019-05-17

Date of Certification Decision:
2022-06-07

Certification Effective Date:
2022-06-07

Certification Expiry Date:
2025-05-16

ISO 13485:2016 CERTIFICATION TM

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

intertek

Calin Moldovean
President, Business Assurance

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