Effective

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

MedXL Inc.

(FIN F000892)

Main Site: 285, Labrosse Street, Pointe-Claire, Québec, H9R 1A3, Canada

Additional Site: 18101 Trans-Canada Highway, Kirkland, Québec, H9J 3Z4 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)

The management system is applicable to:

Design and Manufacture of Drug Preparation, Drug Delivery and Other Single Use Sterile Medical Devices Including: Intravenous Extension Sets, Administration Sets, Intravesical Medication Administration Set, Angiography Kits, Angiography Set, Probe Covers, Smoke Evacuation System Set, Empty Syringe, Saline Syringe, Sodium Citrate Syringe, IVMED Syringe Infuser And service of IVMED Syringe Infuser.

Additional Site: Warehouse

Certificate Number:
0085777-02

Initial Certification Date:
2019-01-04

Date of Certification Decision:
2022-01-31

Certification Effective Date:
2022-01-31

Certification Expiry Date:
2025-01-03

ISO 13485:2016 CERTIFICATION™

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

intertek

Calin Moldovean
President, Business Assurance

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900 Chelmsford Street
Lowell, MA, USA 01851

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