



NSAI

Certificate of Registration of Quality Management System to ISO 13485:2016

Australia-Therapeutic Goods (Medical Devices) Regulations, 2002,

Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure.

Canada - Medical Devices Regulations – Part 1- SOR 98/282

Japan- MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act (,as applicable)

United States- 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D,

21 CFR 820 – Quality System Regulation

The National Standards Authority of Ireland is an MDSAP Recognized Auditing Organization and certifies that:

Delfi Medical Innovations Inc.

106-1099 West 8th Ave.

Vancouver, BC V6H 1C3

Canada

Facility ID: F002521

has been assessed and deemed to comply with the requirements of the above standard and regulations in respect of the scope of operations given below:

The Design, Development, Manufacture, Distribution and Servicing of Tourniquet Systems.

The Design, Development, Manufacture and Distribution of Sterile and Non-Sterile Tourniquet Cuffs.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MP19.4754)

Approved by:

Kevin Mullaney

Director of Certification

Certificate Number: MP19.4754 / Rev 2

Certification Granted: 2019/01/31

Effective Date: 2025/01/31

Expiry Date: 2028/01/30



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Annex to Certificate Number: MP19.4754 / Rev 2

Facility Locations, Scope and Activities

Delfi Medical Innovations Inc.
106-1099 West 8th Ave.
Vancouver, BC
Canada V6H 1C3
File No.: MP19.4754
Facility ID: F002521

Scope: The Design, Development, Manufacture, Distribution and Servicing of Tourniquet Systems. The Design, Development, Manufacture and Distribution of Sterile and Non-Sterile Tourniquet Cuffs

Activities: Administration, Design, Manufacturing, Servicing, Distribution

Delfi Medical Innovations Inc.
6881 Russell Ave.
Burnaby, BC
Canada V5T 4R8
File No.: MP19.4574/A
Facility ID: F002521

Scope: The Manufacture and Distribution of Tourniquet Systems, Sterile, and Non-Sterile Tourniquet Cuffs.

Activities: Manufacturing, Distribution

**Verified by:
Director of Certification**