



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, and Servicing of Tourniquet Systems.
The Design, Development, and Manufacture of Sterile and Non-Sterile Tourniquet Cuffs.**

Japan Only:

**The Design, Development, Manufacture, and Servicing of Tourniquet Systems.
The Design, Development, and Manufacture of Non-Sterile Tourniquet Cuffs.**

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

Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:

Caroline Dore Geraghty
Director of Medical Devices
Head of Notified Body

Certificate Number: MP19.4754/Rev 1
Certification Granted: 2019/01/31
Effective Date: 2022/01/31
Expiry Date: 2025/01/30



National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800
National Standards Authority of Ireland, 20 Trafalgar Square, Nashua, New Hampshire, NH 03063, USA T +1 603 882 4412
All valid certifications are listed on NSAI's website – www.nsaiinc.com The continued validity of this certificate may be verified under "Approved Client Listing"



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Annex to Certificate Number: MP19.4754/Rev 1

Scope of Registration :

**The Design, Development, Manufacture, and Servicing of Tourniquet Systems.
The Design, Development, and Manufacture of Sterile and Non-Sterile
Tourniquet Cuffs.**

Japan Only:

**The Design, Development, Manufacture, and Servicing of Tourniquet Systems.
The Design, Development, and Manufacture of Non-Sterile Tourniquet Cuffs.**

Activity

Location

Administration, Design,
Manufacturing, Servicing,
Distribution

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

Manufacturing

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

**Verified by:
Operations Manager**