EU Quality Management System Certificate
Medical Device Regulation 2017/745

The National Standards Authority of Ireland (NSAI) as a duly designated Notified Body, (identification number 0050) for the purposes of the European Union under MDR 2017/745

APPROVES THE QUALITY MANAGEMENT SYSTEM APPLIED BY

Delfi Medical Innovations, Inc.

106-1099 West 8th Avenue
Vancouver, BC V6H 1C3
Canada

Manufacturer SRN:	CA-MF-000004434
Authorised Representative Name and Address:	International Associates Auditing & Certification Limited The Black Church, St Mary's Place, Dublin 7, Ireland
Device Group:	Delfi Pneumatic Surgical Sterile Disposable Contour Tourniquet Cuffs
Risk Class:	I S

Conclusion: Quality Management System complies with the requirements of Annex XI, Part A of MDR 2017/745. The use of the NSAI Notified Body Identification Number 0050 in conjunction with CE Marking of Conformance for this product is hereby authorised.

Product Certificate Number:	745.043	Re-Issued Date:	n/a
First Issue Date:	14 September 2022	Expiry Date:	13 September 2027
Site Certificate Number:	MD 19.4754		

Signed:

Approved by:
Lisa Donlon
European Medical Device Operations Manager

Approved by:
Dr Majella Geraghty
European Medical Device Operations Manager

CONDITIONS AND LIMITATIONS: this certificate remains valid on condition that the Approved Quality Management System is maintained in an adequate and efficacious manner in line with the requirements of the Regulation. This certificate is based on examination of identified relevant CS, harmonised standards, test reports and audit reports maintained on file with NSAI. Information on examination and tests as per Annex XII, section 10, is available on request. The audit performed by NSAI was limited to the aspects required under Article 52(7). Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI. This certificate is limited to the sterile, measuring or reusable aspect of the device. Substantial Changes to the QMS or the product range covered must receive further approval from NSAI.

The validity of this certificate depends on conditions and/or is limited to the following:

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.

Appendix I			
Certificate History			
Product Certificate Number	Date of Issue	Type of Change *[supplemented, modified or re-issued]*	Details of Change