

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Nipro Canada Corporation
199 Saint David Street
Lindsay
Ontario
K9V 5K7
Canada

Facility ID Number: F003666

Holds Certificate No:

MDSAP 699520

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

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

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, manufacture, sterilization and distribution of Perfusion and Critical Care Assemblies.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2020-04-28

Effective Date: 2025-11-07

Expiry Date: 2028-11-06



BSI Group America Inc. is an MDSAP recognised auditing organization

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