

Certificate US19/81841543

The quality management system of

NuMED Canada, Inc.

45 Second Street West, Cornwall, Ontario, K6J 1G3, Canada

Facility Identification Number: F003192

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate

MDSAP (ISO 13485:2016)

Australia:

Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System

Brazil Jurisdictions

RDC ANVISA n. 16/2013 - Good Manufacturing Practices

RDC ANVISA n. 23/2012

RDC ANVISA n. 67/2009 - Vigilance

Canada:

Medical Devices Regulations – Part 1 SOR 98/282

Japan:

MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ordinance No. 128 (2014) Articles 4 to 68

Japan PMD Act

United States:

21 CFR Part 803 - Medical Device Reporting

21 CFR Part 806 - Reports of Corrections and Removals

21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing

21 CFR Part 820 - Quality System Regulation

For the following activities and devices

Design, manufacture, and contract manufacture of non-sterile and sterile sizing catheters, dilatation, atrioseptostomy, and sterile angiographic catheters

This certificate is valid from Effective Date: 06 July 2022 until Expiry Date: 20 July 2024 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 04 June 2024

Issue 6. Certified since 29 April 2019.

Authorised by

L. Henderson

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