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

SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 - www.sgs.com
SGS United Kingdom Ltd is an MDSAP authorised auditing organization