Certificate US19/81841357

The quality management system of

NuMED, Inc.

2880 Main Street, Hopkinton, NY, 12965, United States Of America

Facility Identification Number: F002669

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, sterile stent placement, occlusion, dilatation, atrioseptostomy, electrode catheters and sterile angiographic catheters and sterile cardiovascular stent, and sterile introducers.
Design, manufacture & contract manufacture of non-sterile and sterile stent placement, dilatation catheters, and sterile cardiovascular stents.

This certificate is valid from Effective Date: 29 June 2022 until Expiry Date: 09 June 2024 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 21 May 2024
Issue 5. Certified since 21 January 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
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