

Certificate US19/81841357

The quality management system of

NuMED, Inc.

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

Facility number: F002669

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

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

Brazil: RDC ANVISA n. 665/2022 - Good Manufacturing Practices; RDC ANVISA n. 551/2021;

RDC ANVISA n. 67/2009 - Vigilance

Canada: Medical Device Regulations SOR/98-282, Part 1

Japan: MHLW Ministerial Ordinance No.169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)

Japan PMD Act (as applicable)

USA: 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, 21 CFR Part 821 - Device Tracking

For the following activities

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

This certificate is valid from Effective date 2024-06-09 until Expiry date 2027-06-09 and remains valid subject to satisfactory surveillance audits.

Issue 8. Certified since 2019-01-21

Certified activities performed by additional sites are listed on subsequent pages.



Authorised by

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SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.



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Certificate US19/81841357, continued
NuMED, Inc.

SGS

MDSAP (ISO 13485:2016)

Issue 8

Sites

NuMED, Inc.
2880 Main Street, Hopkinton, NY, 12965, United States Of America

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

NuMED Canada, Inc.
45 Second Street West, Cornwall, Ontario, K6J 1G3, Canada

Facility number: F003192

Design, manufacture and contract manufacture of sterile sizing catheters, sterile dilatation, and sterile atrioseptostomy catheters.



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