

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; RDC ANVISA n. 551/2021; RDC ANVISA n. 67/2009

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; 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

Design, manufacture and contract manufacture of non-sterile and sterile sizing catheters, sterile stent placement, occlusion, dilatation, atrioplastomy, electrode catheters and sterile angiographic catheters and sterile cardiovascular stent, and sterile introducer.

This certificate is valid from Effective date 2023-01-06 until Expiry date 2024-06-09 and remains valid subject to satisfactory surveillance audits.

Issue 7. Certified since 2019-01-21

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



Authorised by
Geoffrey De Visscher
Head of Notified Body 1639

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

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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NuMED, Inc.



MDSAP (ISO 13485:2016)

Issue 7
Sites
<p>NuMED, Inc. 2880 Main Street, Hopkinton, NY, 12965, United States Of America</p> <p>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 introducer.</p>
<p>NuMED Canada, Inc. 45 Second Street West, Cornwall, Ontario, K6J 1G3, Canada</p> <p>Design, manufacture and contract manufacture of non-sterile and sterile sizing catheters, dilatation, atrioseptostomy and sterile angiographic catheters.</p>



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