

Certificate Number US19/81841543

SGS

The quality management system of

NuMED Canada, Inc.

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

Dun & Bradstreet D-U-N-S identification number : 25-086-1747

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 (excluding Part 1.6)
– Full Quality Assurance Procedure (including design)

Brazil:

RDC ANVISA n. 16/2013 / RDC ANVISA n. 23/2012 / RDC ANVISA n. 67/2009

Canada:

Medical Devices Regulations – Part 1 SOR 98/282

Japan:

MHLW Ministerial Ordinance 169, Article 4 to Article 68 / PMD Act

United States:

21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D / 21 CFR 821

For the following activities and devices

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

This certificate is valid from

Effective Date: 2019-04-30 until Expiry Date: 2022-04-28
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 2021-07-13

Issue 2. Certified since 2019-04-29

Authorised by J Hall
Business Manager

SGS United Kingdom Ltd

202B Worle Parkway, Weston-super-Mare, BS22 6WA, UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

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