



Certificate Number US19/81841357

The quality management system of

NuMED, Inc.

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

Dun & Bradstreet D-U-N-S identification number: 11-418-6877

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

For the following activities and devices

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

This certificate is valid from

Effective Date: 2019-01-22 until Expiry Date: 2022-01-20
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 2021-05-18

Issue 2. Certified since 2019-01-21

Authorised by H Crick
Business Manager

SGS United Kingdom Ltd

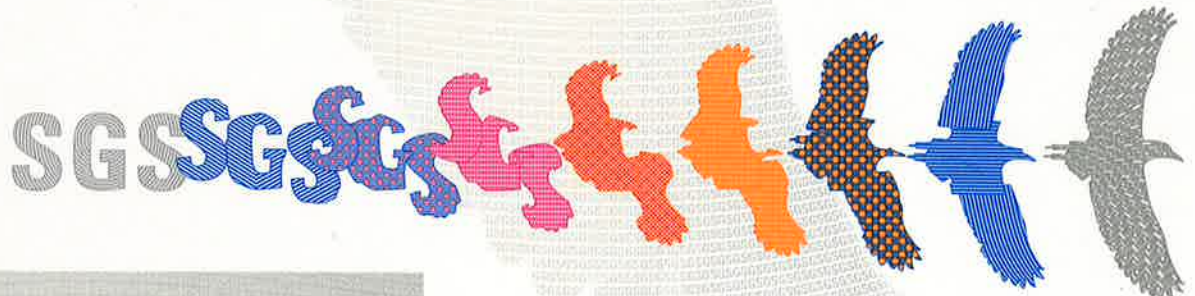
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK

t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

SGS United Kingdom Ltd is an MDSAP authorised auditing organization

SGS MDSAP 1116

Page 1 of 1



This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <http://www.sgs.com/en/certified-clients-and-products/certified-client-directory>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.