EC Certificate Full Quality Assurance System: Certificate US19/819943546

The management system of

NuMED, Inc.

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

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate

This certificate is valid from 26 March 2021 until 28 February 2024
and remains valid subject to satisfactory surveillance audits.
Issue 4. Certified since 05 November 1998

Certification is based on reports numbered WW/MC 09581

Authorised by

Digitally signed by Ostapciuc Alexandr
Date: 2022.11.14 15:45:32 EET
Reason: MoldSign Signature
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NuMED, Inc.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 4

Detailed scope

Sterile Z-5 Atrioseptostomy Catheters; Sterile Tyshak, Tyshak-X, Tyshak Mini, Tyshak II, Tyshak NuCLEUS, Z-Med, Z-Med-X, Z-Med II, Z-Med II-X, NuCLEUS-X and COEfficient Percutaneous Transluminal Valvuloplasty Catheters and Sterile Mullins-X Ultra High Pressure Dilatation Catheter (PTV); PTA Catheters, Sterile Percutaneous Transluminal Angioplasty (PTA) catheters; Sterile PTS and PTS-X Percutaneous Transluminal Sizing Catheters; Sterile MULTI-TRACK Angiographic Catheters; Sterile Bonhoeffer Multi-Track Mitral Dilatation Kit; Sterile REBOA Balloon; Sterile Balloon In Balloon (BIB) Stent Placement Catheter; Sterile Cheatham Platinum (CP) Stent (Covered & Bare); Sterile Mounted CP Stent & Covered Mounted CP Stent with BIB Delivery System; Sterile NuDEL Delivery System, and sterile D'VILL Introducer for Introduction of balloons, catheters and other diagnostic and interventional devices.

Class I Sterile: "Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions": Sterile Tear Duct Catheter

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.