By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 622285**

Issued To: **Navilyst Medical, Inc.**
26 Forest Street
Marlborough
Massachusetts
01752
USA

In respect of:

Design and manufacture of sterile central venous and peripheral catheters, dialysis catheters, implantable infusion ports, absorbable plug and delivery systems, catheter introducer kits, drainage catheters, guidewires, fluid administration, management, and pressure monitoring devices; and associated accessories.
Design and manufacture of non-sterile fluid administration, management, and pressure monitoring devices.
Those aspects related to obtaining and maintaining sterility in the manufacture of torque devices.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2015-02-23** Date: **2020-07-29** Expiry Date: **2024-05-26**

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Supplementary Information to CE 622285

Issued To:

Navilyst Medical, Inc.
26 Forest Street
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Number	Device Name	Intended purpose
Class III		
---	Angiographic guidewires	See CE 622286
---	Xcela Power Injectable PICC	See CE 622294
---	Xcela PICC with PASV Valve Technology Xcela Hybrid PICC with PASV Valve Technology	See CE 622296
---	BioFlo™ PICC with ENDEXO™ Technology	See CE 622297
---	BioFlo™ PICC with ENDEXO™ and PASV™ Valve Technology BioFlo™ Hybrid PICC with ENDEXO™ and PASV™ Valve Technology	See CE 622299
---	BioFlo™ DuraMax with Endexo Technology Chronic Hemodialysis Catheter and accessories	See CE 623831
---	BioSentry™ Tract Sealant System	See CE 710508

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Number	Device Name	Intended purpose
Class IIb		
MD 0204, MDS 7006	Drainage Catheters	Drainage Catheters are intended for percutaneous drainage.
MD 0102, MDS 7006	Peripheral Vascular Catheters	Peripheral Vascular Catheters are intended for short term access to the peripheral venous system.
Class IIa		
MD 0102, MD 0106, MD 1104, MDS 7006	Fluid administration, management, and pressure monitoring devices	---
MD 0106, MDS 7006	Catheter Introducer Kits	---
Class I (s)		
MDS 7006	Torque Devices	---

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 622285**
Date:	**2020-07-29**
Issued To:	**Navilyst Medical, Inc.** **26 Forest Street** **Marlborough** **Massachusetts** **01752** **USA**

Subcontractor:	**Service(s) supplied**
AngioDynamics, Inc. also D.B.A. Navilyst Medical, Inc. 10 Glens Falls Technical Park Glens Falls New York 12801 USA	**Manufacture**
AngioDynamics, Inc. also D.B.A. Navilyst Medical, Inc. 603 Queensbury Avenue Queensbury New York 12804 USA	**Manufacture**
C R Bard 289 Bay Road Queensbury New York 12804 USA	**Control of Sterilization** **Manufacture** **Packaging**

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Subcontractor:	**Service(s) supplied**
Coldstream Laboratories, Inc. 1575 McGrathiana Parkway Lexington Kentucky 40511 USA	**Crucial Supplier**
Donawa Lifescience Consulting Piazza Albania, 10 Rome 00153 Italy	**EU Representative**
Freudenberg Medical MIS, Inc 2301 Centennial Boulevard Jeffersonville IN 47130 USA	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Heraeus Medical Components, LLC 2605 Fernbrook Lane, Suite J Plymouth Minnesota 55447 USA	**Manufacture**
Isomedix Operations, Inc 43425 Business Park Drive Temecula California 92590 USA	**ETO Sterilization**
Isomedix Operations, Inc 3459 South Clinton Avenue South Plainfield New Jersey 07080 USA	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
Pelham Plastics Inc. 42 Dick Tracy Drive P.O. Box 997 Pelham New Hampshire 03076-0967 USA	**Manufacture**
Sterigenics US, LLC 84 Park Road Queensbury New York 12804 USA	**ETO Sterilization**
Surgical Specialties Mexico S. DE R.L. DE C.V. also trading as Surgical Specialties Corporation Corredor Tijuana-Rosarito 2000 #24702-B, Ejido Francisco Villa Tijuana, B.C., C.P. 22235 Mexico	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 622285**
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Date	Reference Number	Action
23 February 2015	8247012	First Issue -Transfer from another Notified Body.
05 May 2015	8332159	Certificate renewal. EU representative added to the list of subcontractors.
7 March 2019	9668536	Extension to scope to include non-sterile fluid administration, management and pressure monitoring devices
13 March 2019	8247071	Traceable to NB 0086.
07 January 2020	9759300	Certificate renewal. Administrative edits to multiple subcontractor names/addresses for consistency with ISO certificates. Add device table.
22 May 2020	3217859	Certificate update. CE 622290 and CE 622292 cancelled and removed.
16 July 2020	3215970	Extension to scope for "absorbable plug and delivery system" and addition of BioSentry™ Tract Sealant System to device table. Addition of subcontractors Isomedix Operations, Inc. Temecula California, Surgical Specialties Mexico Tijuana and Coldstream Laboratories, Inc. Lexington Kentucky.
Current	3216778	Addition of subcontractor AngioDynamics, Inc. also D.B.A. Navilyst Medical, Inc., 603 Queensbury Avenue, Queensbury, New York.