By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 677471**

Issued To: **Go Medical Industries Pty Ltd**
200 Churchill Avenue
Subiaco
Western Australia
6008
Australia

In respect of:

Design and manufacture of:
- sterile V-Sets
- sterile Flow Control Tubing
- non sterile spring driven infusion pumps
- sterile Amniotomy Devices
Those aspects of Annex II concerned with securing and maintaining the sterility of urinary catheters.

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: **2018-03-21** Date: **2020-10-29** Expiry Date: **2023-03-20**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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Supplementary Information to CE 677471

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Number	Device Name	Intended Purpose per IFU
Class IIa		
NBOG code: MD0102 GMDN: 16649	Multi-line access to patient line: V-sets	LA VSE 720: The V-Set is intended to be connected to a patient's port or cannula via a luer lock fitting to provide multiple line access to a single site. Once the V-set is connected to a patient, infusions or bolus doses can be administered by connecting the relevant pump, syringe or drip set to the line required. The V-set is available in various configurations with one-way valves on the lines depending on the configuration selected.
NBOG code: MD0102 GMDN: 16649	Flow Control Tubing: FCT	LA FCT 747, LA FCT 748, LA FCT 750 : For the continuous controlled infusion of medication via subcutaneous or intravenous administration when used in conjunction with the Go Medical Springfusor. A range of flow control tubing (FCT) models with various infusion rates are available

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Number	Device Name	Intended Purpose per IFU
		LA FCT 778: The Gomedical Medical Intravenous Flow Control Tubing (FCT) is intended to be used with O'Neil Springfusor 50/60 (REF: SF5060) and B.Braun Omnifix 50 mL Syringe (REF: 4617509F) to provide intermittent or continuous intravenous infusion or medication at the specified flow rate. The springfusor and FCT system can be used for ambulatory or immobile inpatients and patients at home
NBOG code: MD0106 GMDN: 12990	Amniotomy device: Amnicot	The Amnicot is a single-use fingercot designed for performing amniotomies (artificial rupture of amniotic membrane).
Class IIb		
NBOG Code: MD1101 GMDN: 46845	Spring Driven Infusion Pump: SpringFusor	The springfusor is suitable for intermittent or continuous infusion of medication via intravenous or subcutaneous means. It can be used for ambulatory or immobile patients in clinical or home settings

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List of Significant Subcontractors

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

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Date:	**2020-10-29**
Issued To:	**Go Medical Industries Pty Ltd** **200 Churchill Avenue** **Subiaco** **Western Australia** **6008** **Australia**

Subcontractor:	**Service(s) supplied**
Advena Ltd Tower Business Centre 2nd Floor, Tower Street Swatar BKR 4013 Malta	**EU Representative**
Bioster, a.s. Tejny 621 664 71 Veverska Bityska Czech Republic	**Radiation (Gamma Sterilization)**
GMMI SDN. BHD. No 12, Persiaran Industri Rapat 2 Perindustrian Ringan Sri Rapat 31350 Ipoh Perak Malaysia	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Greenleaf Medical Products Pte Ltd Unit 01-12, BLK 1003 Bukit Merah Central Redhill Industrial Estate Singapore 159836 Singapore	**Manufacture**
SC HENNING ENTERPRISES EUROPE SRL B-dul Poiters No 14 Lasi 7000671 Romania	**Manufacture**
Steritech Pty Ltd 160 South Gippsland Highway Dandenong South Victoria 3175 Australia	**Radiation (Gamma Sterilization)**

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Subcontractor:	**Service(s) supplied**
Synergy Health Allershausen GmbH Kesselbodenstrasse 7 Allershausen D-85391 Germany	**Radiation (Gamma Sterilization)**
Synergy Sterilisation Rawang (M) Sdn. Bhd. Lot 42, Jalan Industri 2/1 Rawang Intergrated Industrial Park Rawang Selangor 48000 Malaysia	**Radiation (Gamma Sterilization)**

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
21 March 2018	8767641	First issue.
26 July 2018	9627141	Extension to scope for sterile V-Sets. The addition of Greenleaf Medical Products Pte Ltd. as significant subcontractor for the service of manufacture. The addition of Steritech Pty Ltd as significant subcontractor for the service of gamma sterilisation.
27 February 2019	8904038	Traceable to NB 0086.
2 July 2019	9750628	Extension to scope to include Flow Control Tubing. Change of address of EU representative Advena Ltd to Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013, Malta.
28 October 2019	3066986	Certificate Scope Extension to include Sterile Amniotomy Devices.
Current	3270702	Scope extension to include spring driven infusion pump, addition 3 of critical subcontractors: GMMI, Synergy health Germany and Synergy health Malaysia

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