EC Certificate - Full Quality Assurance System

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

No. **CE 644823**

Issued To: **Southmedic Inc.**
50 Alliance Blvd
Barrie
Ontario
L4M 5K3
Canada

In respect of:

Design, development and manufacture of open oxygen delivery device with carbon dioxide monitoring; oxygen mask with carbon dioxide monitoring; tubing connectors, nasal cannula, adult and pediatric face masks (aerosol and oxygen); sterile surgical blades, sterile disposable and safety scalpels and non-sterile vaginal pessary for the treatment of stress incontinence.

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: **2016-01-23** Date: **2020-07-03** Expiry Date: **2023-01-10**

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Supplementary Information to CE 644823

Issued To:

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0101	Open oxygen delivery device (aerosol)	--
MD 0101	Open oxygen delivery device (oxygen)	--
MD 0101	Open oxygen delivery device with carbon dioxide monitoring	--
MD 0101	Oxygen mask with carbon dioxide monitoring	--
MD 0101	Nasal cannula and Nasal cannula with CO_2 monitoring	--
MD 0101	Multi-dose inhaler (MDI) adaptor	--
MD 0106	Sterile Surgical Blades	--
MD 0106	Sterile Disposable and Safety Scalpels	--
MD 0204	Non-sterile vaginal pessary	--

First Issued: **2016-01-23** Date: **2020-07-03** Expiry Date: **2023-01-10**

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By Royal Charter

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List of Significant Subcontractors

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

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Subcontractor:	**Service(s) supplied**
Covidien 6135 Gunbarrel Ave Boulder Colorado 80301 USA	**Manufacture**
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	**EU Representative**
Sterigenics EO Canada, Inc. 781 Pharmacy Avenue Toronto Ontario M1L 3K2 Canada	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 644823**
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Date	Reference Number	Action
23 January 2016	8432655	Transfer from another Notified Body.
12 July 2017	8764391	Change of EU Rep address.
11 January 2018	8886083	CE Renewal. Removal of Wound Closure System from scope expression. Removal of Pepin Manufacturing as manufacturing subcontractor.
26 February 2019	8679712	Traceable to NB 0086.
26 May 2020	3164292	Addition of critical subcontractor Covidien. Addition of supplementary device table. Name Correction Steris Applied Sterilization Technologies. Reduction to scope: removal of non-sterile blades and scalpels.
Current	3232794	Reduction in scope: removed tracheostomy oxygen masks from certificate scope and from supplementary device table. Removal of subcontractor 'STERIS Applied sterilization technologies.'