

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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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.

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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	--

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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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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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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.'

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