By Royal Charter

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); Tracheostomy oxygen masks; Sterile and non-sterile surgical blades, sterile and non-sterile disposable and safety scalpels, sterile Wound closure System, (includes elastomer tubes and cords , elastomer retainers , anchors, canulators, wound closure strips, lancet, adhesive anchors, button tails), 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 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2016-01-23** Date: **2017-07-12** Expiry Date: **2018-01-10**

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

List of Significant Subcontractors

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

Certificate No:	**CE 644823**
Date:	**2017-07-12**
Issued To:	**Southmedic Inc.** **50 Alliance Blvd** **Barrie** **Ontario** **L4M 5K3** **Canada**

Subcontractor:	**Service(s) supplied**
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	**EU Representative**
Pepin Manufacturing, Inc. 1875 Highway 61 South Lake City Minnesota 55041 USA	**Manufacture**
Sterigenics EO Canada, Inc. 781 Pharmacy Avenue Toronto Ontario M1L 3K2 Canada	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
Steris Isomedix Services 184 Crown Court Whitby Ontario L1N 7B1 Canada	**Gamma Sterilization**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 644823**
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50 Alliance Blvd
Barrie
Ontario
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Date	Reference Number	Action
23 January 2016	8432655	Transfer from another Notified Body.
Current	8764391	Change of EU Rep address.