By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 644824**

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

In respect of:

Manufacture of Sterile Wound Closure System (includes elastomer cords, elastomer retainers, anchors, cannulators,wound closure strips, lancet, adhesive anchors, button tails, and surgical retainers).
Those aspects of manufacture related to securing and maintaining sterility of topical elastic traction devices for presurgical skin expansion and wound stabilization.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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: **2020-04-20** Expiry Date: **2023-01-10**

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Supplementary Information to CE 644824

Issued To:

Southmedic Inc.
50 Alliance Blvd
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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0303	Wound closure set	N/A
Class Is		
MD 0303	Topical Elastic Traction devices	N/A

First Issued: **2016-01-23** Date: **2020-04-20** Expiry Date: **2023-01-10**

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List of Significant Subcontractors

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

Certificate No:	**CE 644824**
Date:	**2020-04-20**
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**
Implantech Associates, Inc. 6025 Nicolle Street, Suite B Ventura CA 93003 USA	**Manufacture**
Pepin Manufacturing, Inc. 1875 Highway 61 South Lake City Minnesota 55041 USA	**Manufacture**

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Subcontractor:	**Service(s) supplied**
STERIS Applied Sterilization Technologies ULC 184 Crown Court Whitby Ontario L1N 7B1 Canada	**Radiation (Gamma Sterilization)**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 644824**
Date: **2020-04-20**
Issued To: **Southmedic Inc.**
50 Alliance Blvd
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Date	Reference Number	Action
23 January 2016	8432658	Transfer from another Notified Body.
12 July 2017	8764392	Change to EU Rep address.
11 January 2018	8886062	CE Renewal.
06 February 2019	8679712	Traceable to NB 0086.
01 April 2019	9676415	Scope extension to include Wound Closure System and add "wound stabilization" to intended use for Topical Elastic Traction device.
Current	3164299	Scope extension to include "surgical retainers". Addition of critical subcontractor Implantech. Change of subcontractor name "Steris Isomedix Services" to "STERIS Applied Sterilization Technologies ULC".