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:

Those aspects of manufacture related to securing and maintaining sterility of topical elastic traction devices for pre-surgical skin expansion

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):

Albert Roossien, Regulatory Lead

First Issued: **2016-01-23** Date: **2019-02-26** Expiry Date: **2023-01-10**

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

List of Significant Subcontractors

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

Certificate No:	**CE 644824**
Date:	**2019-02-26**
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**
Steris Isomedix Services 184 Crown Court Whitby Ontario L1N 7B1 Canada	**Gamma Sterilization**

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EC Certificate - Production Quality Assurance Certificate History

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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.
Current	8679712	Traceable to NB 0086.