

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 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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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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List of Significant Subcontractors

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

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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.
Current	8764392	Change to EU Rep address.

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