

# 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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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.

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**

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.

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