By Royal Charter

EC Certificate - Production Quality Assurance

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

No. **CE 670403**

Issued To: **SunMed LLC**
2710 Northridge Dr NW Suite A
Grand Rapids
Michigan
49544
USA

In respect of:

The manufacture of sterile tracheal tubes and tracheostomy tubes

Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of disposable laryngoscope handles, laryngoscope blades and eye protectors

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: **2017-07-25** Date: **2019-03-18** Expiry Date: **2022-07-24**

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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 670403**
Date:	**2019-03-18**
Issued To:	**SunMed LLC** **2710 Northridge Dr NW Suite A** **Grand Rapids** **Michigan** **49544** **USA**

Subcontractor:	**Service(s) supplied**
mdi Europa GmbH Langenhagener Str. 71 Hannover-Langenhagen 30855 Germany	**EU Representative**
MEDICAL DEVICES (PVT) LTD Wazirabad Road, Ugoki Sialkot Punjab 51050 Pakistan	**Manufacture**
Sumai Plastic Products (Suzhou) Co., Ltd No. 12 East Chunshen Lake Road Xiangcheng Economic Developing Dist Suzhou Jiangsu 215000 China	**Manufacture**

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Subcontractor:	**Service(s) supplied**
TECNO INSTRUMENTS (PVT) LTD 316-C Small Industrial Estate Sialkot Punjab 51340 Pakistan	**ETO Sterilization**
Vention Medical, Inc. 520 Watson SW Grand Rapids Michigan 49504 USA	**ETO Sterilization**
Well Lead C-4 Jinhu Industrial State Hualong, Panyu Guangzhou 511434 China	**Finished Device Supplier**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 670403**

Date: **2019-03-18**

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Date	Reference Number	Action
25 July 2017	8707838	New Annex V certificate replacing OBL certificates.
Current	8891662	Traceable to NB 0086.