

EC Certificate - Production Quality Assurance

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

No. CE 638746
Issued To: Sunny Medical Device
(Shenzhen) Co., Ltd.
1/F and 401
Zhongtianxin Building B
Longgang District
Shenzhen
Guangdong
518172
China

In respect of:

The manufacture and sterilization of manifold and stopcocks, guide wires, haemostatic valves, pressure lines, disposable needles, disposable inflation device kits and disposable manifold kits.

Those aspects of Annex V relating to securing and maintaining sterile conditions during manufacture of disposable balloon inflation devices, control syringes, disposable TR-closure band/Radiseals, disposable angio-closure pads, disposable heparin caps and disposable towel sheet clips

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: **2015-09-01**

Date: **2019-03-08**

Expiry Date: **2023-03-03**

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Page 1 of 2

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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Supplementary Information to CE 638746

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NBOG code(s)	Device description	Intended purpose
Class IIa		
MD0102 MDS7006	Manifold and stopcocks	Not applicable for class IIa devices
	Haemostatic valves	
	Pressure lines	
	Disposable manifold kits	
MD0106 MDS7006	Guide wires	
	Disposable needles	
	Disposable inflation device kits	
Class Is		
MD0102 MDS7006	Disposable balloon inflation devices	Not applicable for class Is devices
	Control syringes	
MD0106 MDS7006	Disposable heparin caps	
	Disposable towel sheet clips	
MD0301 MDS7006	Disposable TR-closure/Radiseals	
	Disposable angio-closure pads	

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List of Significant Subcontractors

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

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Longgang District
Shenzhen
Guangdong
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Subcontractor:

Service(s) supplied

AS Medical
Waalsdorperweg 345
2597HZ The Hague
The Netherlands

EU Representative

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 638746**
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Date	Reference Number	Action
01 September 2015	8364795	First issue, transfer from another Notified Body.
18 October 2017	8712314	Company addresses updated following relocation. Certificate scope updated to reflect classification for disposable balloon inflation devices.
08 February 2018	8803265	Certificate renewal.
07 March 2019	9719509	Change to European Representative address. Addition of Supplementary Product Information table.
Current	8693529	Traceable to NB 0086.