EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 647943**

Issued To: **Inovytec Medical Solutions Ltd**
3 Hanagar St.
Hod Hasharon
4501306
Israel

In respect of:

The design and manufacture of mobile cardiac and respiratory emergency care, remote respiratory monitoring equipment and emergency portable ventilator equipment.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 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: **2017-06-12** Date: **2019-02-19** Expiry Date: **2022-06-11**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 647943

Issued To:

Inovytec Medical Solutions Ltd
3 Hanagar St.
Hod Hasharon
4501306
Israel

Number	Device Name	Intended purpose per IFU
Class IIb		
MD 1102 MD 1103 MD 1302 MDS 7010	Sali D	The Sali D is intended for use in conscious and unconscious medical emergencies on someone showing signs of physical distress. This includes airway management, oxygen therapy, defibrillation and vital signs monitoring, and the ability to provide remote monitoring when required.
MD 1102 MDS 7010	Ventway Sparrow	The Ventway Sparrow ventilator is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation.

First Issued: **2017-06-12** Date: **2019-02-19** Expiry Date: **2022-06-11**

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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

Certificate No:	**CE 647943**
Date:	**2019-02-19**
Issued To:	**Inovytec Medical Solutions Ltd** **3 Hanagar St.** **Hod Hasharon** **4501306** **Israel**

Subcontractor:	**Service(s) supplied**
Beijing M&B Electronic Instruments Co., Ltd Room 6319,Building 1, No. 27, Yongwang Road, Daxing Bioengineering and Medicine Industry Base Zhongguancun Science Park, Daxing District Beijing 102629 China	**Manufacture**
Beijing National Medical Co.,Ltd Room 208, Section A Innovation Building #29 Life Science Park Road Changping District Beijing 102206 China	**Manufacture**

...making excellence a habit.™

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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

Certificate No:	**CE 647943**
Date:	**2019-02-19**
Issued To:	**Inovytec Medical Solutions Ltd** **3 Hanagar St.** **Hod Hasharon** **4501306** **Israel**

Subcontractor:	**Service(s) supplied**
Obelis S.A Boulevard General Wahis 53 Brussels 1030 Belgium	**EU Representative**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 647943**

Date: **2019-02-19**

Issued To: **Inovytec Medical Solutions Ltd**
3 Hanagar St.
Hod Hasharon
4501306
Israel

Date	Reference Number	Action
12 June 2017	8465848	Initial Issue
31 October 2018	9628596	Extension to Scope. Ventway Sparrow ventilator added into product range.
Current	8868093	Traceable to NB 0086.

...making excellence a habit.™

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.