

# EC Certificate - Full Quality Assurance System

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

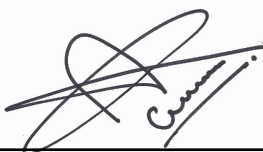
**No.** CE 647943  
**Issued To:** **Inovytec Medical Solutions Ltd**  
**3 Hanagar St.**  
**Hod Hasharon**  
**4501306**  
**Israel**

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**

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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 647943

Issued To:

**Inovytec Medical Solutions Ltd**  
**3 Hanagar St.**  
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| Number                                    | Device Name     | Intended purpose per IFU   |
|---|-----------------|--|
| <b>Class IIb</b>                          |                 |  |
| MD 1102<br>MD 1103<br>MD 1302<br>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<br>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.   |

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## List of Significant Subcontractors

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

Certificate No: **CE 647943**  
Date: **2019-02-19**  
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**3 Hanagar St.**  
**Hod Hasharon**  
**4501306**  
**Israel**

**Subcontractor:**

**Service(s) supplied**

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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**

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Beijing National Medical Co., Ltd  
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Changping District  
Beijing  
102206  
China

**Manufacture**

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**Israel**

**Subcontractor:**

**Service(s) supplied**

Obelis S.A  
Boulevard General Wahis 53  
Brussels  
1030  
Belgium

**EU Representative**

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# EC Certificate - Full Quality Assurance System

## Certificate History

Certificate No: **CE 647943**  
 Date: **2019-02-19**  
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| 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.  |

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