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By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 662942**

Issued To: **BNOS Meditech**
9 Fifth Avenue
Bluebridge Industrial Estate
Halstead
Essex
CO9 2SZ
United Kingdom

In respect of:

The design and manufacture of Meditech range of medical gas regulators, with and without therapy outlet. The design and manufacture of demand valves for use with medical gases including delivery systems for pre-mixed nitrous oxide and oxygen mixtures. The design and manufacture of the MicroVENT resuscitator, its derivatives and variants. The design and manufacture of low pressure medical gas hose assemblies, including associated connectors.

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):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2016-12-05** Date: **2021-05-19** Expiry Date: **2023-10-19**

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Supplementary Information to CE 662942

Issued To:

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NBOG Code(s)	Device Name	Intended purpose per IFU
Class IIb		
MD 1112	Medical gas regulators	Units fitted with a pressure outlet are used to provide gas to a device which requires an input at this pressure. Units fitted with a flow outlet are used to deliver variable flow rates of gas to a patient who requires gas therapy
Class IIa		
MD 1112	Medical gas connectors	n/a Class IIa
MD 1112	Low pressure hose assemblies	n/a Class IIa
MD 1102	Demand valves for resuscitators	n/a Class IIa
MD 1102	MicroVent Rescuscitators	n/a Class IIa

First Issued: **2016-12-05** Date: **2021-05-19** Expiry Date: **2023-10-19**

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List of Significant Subcontractors

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

Certificate No:	**CE 662942**
Date:	**2021-05-19**
Issued To:	**BNOS Meditech** **9 Fifth Avenue** **Bluebridge Industrial Estate** **Halstead** **Essex** **CO9 2SZ** **United Kingdom**

Subcontractor:	**Service(s) supplied**
Medical Device Management Ltd Block B, The Crescent Building Northwood Santry Dublin 9 D09 C6X8 Ireland	**EU Representative**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 662942**
Date: **2021-05-19**
Issued To: **BNOS Meditech**
9 Fifth Avenue
Bluebridge Industrial Estate
Halstead
Essex
CO9 2SZ
United Kingdom

Date	Reference Number	Action
05 December 2016	8630730	First issue. Transfer from another Notified Body.
19 October 2018	8998166	Renewal. Scope amended to include statement 'The design and manufacture of demand valves for use with medical gases including delivery systems for pre-mixed nitrous oxide and oxygen mixtures.'
19 February 2019	8892330	Traceable to NB 0086.
Current	3445000	Addition of `The design and manufacture of low pressure medical gas hose assemblies, including associated connectors ` to scope. Addition of EU Representative. Addition of product table.

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Meditech
9, Fifth Avenue
Bluebridge Industrial Estate
Halstead
Essex CO9 2SZ
United Kingdom

T: +44 (0) 1787 479475
F: +44 (0) 1787 477747

E-mail: sales@meditech.uk.com
www.meditech.uk.com

CE Certification Extension of certificate number CE 662942

Manufacturer name	B.N.O.S. Meditech Ltd
Manufacturer address and contact details	9, Fifth Avenue, Bluebridge Industrial Estate, Halstead, Essex, CO9 2SZ, UK. sales@medietch.uk.com
Single Registration Number (SRN)	GB-MF-000008883

Authorised Representative name	Medical Device Management Ltd (MDM)
Authorised Representative address and contact details	Block B, The Crescent Building, Northwood, Santry, Dublin 9, DO9 C6X8 Eu-Rep@medicaldevicemanagement.com
Single Registration Number (SRN)	IE-AR-000002496

Relating to the following medical Devices: Medical gas regulators, Medical gas connectors, Low pressure hose assemblies, Demand valves for resuscitators and MicroVENT Resuscitators.

This is to certify that expiry date of CE certificate as per the number stated above has been extended based on proposal 2023/0005 (COD) resulting in regulation 2023/607 which was approved and published in the Official Journal of the European Union Volume 66 on 20th March 2023.

The transitional period and the concomitant extension of the certificate's validity is automatic by European law, provided the conditions laid down in Article 120(3c) MDR are fulfilled. We hereby declare that these requirements have been fulfilled as explained below and the expiry date of the certificate is now **31 December 2028** while certain conditions are fulfilled.

The published legislative text indicates that the transition period for low-medium risk medical devices is extended from 26 May 2024 until 31 December 2028, during this period Notified Bodies cannot issue new certificates but Manufactures may issue a self-declaration and Competent Authorities may issue certificates of free sale.

We can herby confirm that an MDR agreement/contract reference number Q577663 dated July 2021 has been signed by the manufacturer and our notified body (BSI Identifier 2797) and therefore subject to ongoing Notified Body conformity assessment procedures and additional conditions set out below the expiry date of the certificate is extended until **31 December 2028**:

(a) the devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;

(b) there are no significant changes in the design and intended purpose;

(c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;

(d) no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9);

NOTE: B.N.O.S. Meditech Ltd have already achieved this with a successful onsite MDR assessment conducted by BSI in July 2022 and annual continuous MDR surveillance audits 2023, 2024 and 2025.

(e) no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph of Annex VII for conformity assessment in respect to the device or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII.

Therefore, as a device transitioning to MDR, having met the applicable conditions the certificate stated above shall be recognised as being valid beyond the expiry date and until the end of December 2028 enabling the manufacturer to continue to place the specified devices on the market based on the existing certificate and conditions stated above.

Signed under the sole responsibility of the legal manufacturer

Name: Sophie Gugacz

Signed: Sophie Gugacz

Role: Quality Manager

Date: 13th January 2026