

# 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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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.

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## Supplementary Information to CE 662942

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NBOG Code(s)	Device Name	Intended purpose per IFU
<b>Class IIb</b>		
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
<b>Class IIa</b>		
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 Resuscitators	n/a Class IIa

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## List of Significant Subcontractors

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

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**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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## Certificate History

Certificate No: **CE 662942**  
 Date: **2021-05-19**  
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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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12 June 2023

**Notified Body Confirmation Letter**  
**Reference: EU2023-607/642105**

To whom it may concern,

**Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices**

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

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

SRN Number (if available): GB-MF-000008883

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Dr Dan Taylor  
BSI Scheme Manager

**Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
MicroVENT Resuscitators	Class IIa	N/A	CE 662942
Medical gas regulators	Class IIb excluding Class IIb implantable non-WET	N/A	CE 662942
Low pressure hose assemblies	Class IIa	N/A	CE 662942
Demand valves	Class IIa	N/A	CE 662942

### Confirmation Letter Revision History

Date	Action
12 June 2023	Initial Issue

## CE Certification Extension of certificate number CE 662942

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 20<sup>th</sup> 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 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 hereby confirm that an MDR agreement/contract reference number Q577663 dated July 2021 has been signed by the manufacturer and our notified body (BSI) 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.
- (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 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  
Role Quality Manager  
Date 02<sup>nd</sup> May 2024