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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.

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

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