

# 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**

...making excellence a habit.™

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.

# EC Certificate - Full Quality Assurance System

## Supplementary Information to CE 662942

Issued To:

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

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

First Issued: **2016-12-05**

Date: **2021-05-19**

Expiry Date: **2023-10-19**

...making excellence a habit.™

Page 2 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.

# 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 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**

...making excellence a habit.™

# 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.

...making excellence a habit.™

Page 1 of 1

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.