

UKCA Certificate - Full Quality Assurance System

Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

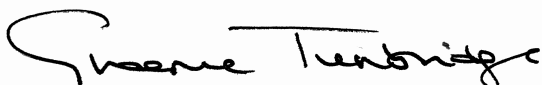
No.	UKCA 754817
Issued To:	BNOS Meditech
	9 Fifth Avenue
	Bluebridge Industrial Estate
	Halstead
	CO9 2SZ
	United Kingdom

In respect of:

The design, manufacture and final inspection of Meditech range of medical gas regulators, with and without therapy outlet. The design, manufacture and final inspection of demand valves for use with medical gases including delivery systems for pre-mixed nitrous oxide and oxygen mixtures. The design, manufacture and final inspection of the MicroVENT resuscitator, its derivatives and variants. The design, manufacture and final inspection 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 Part II of the Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class III products an Annex II (modified as described above) Section 4 certificate is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2023-02-02**

Date: **2023-02-02**

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 regulation as demonstrated through the required surveillance activities of the Approved Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000

Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London, W4 4AL, UK.

A member of BSI Group of Companies.

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Supplementary Information to UKCA 754817

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NBOG / UKCA 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 Resuscitators	n/a Class IIa

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Certificate History

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Date	Reference Number	Action
Current	3494888	First Issue; Traceable to CE 662942.

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