EC Certificate - Full Quality Assurance System

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

No. **CE 58024**

Issued To: **Bedfont Scientific Limited**
Station Road
Harrietsham
Maidstone
Kent
ME17 1JA
United Kingdom

In respect of:

The design and manufacture of gas monitors for medical purposes.

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: **2001-03-08** Date: **2021-03-05** Expiry Date: **2024-05-26**

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Supplementary Information to CE 58024

Issued To:

Bedfont Scientific Limited
Station Road
Harrietsham
Maidstone
Kent
ME17 1JA
United Kingdom

NBOG Code	Device Name	Intended purpose per IFU
Class IIa		
MD 1102	Gas monitors	N/A for Class IIa

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By Royal Charter

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List of Significant Subcontractors

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

Certificate No:	**CE 58024**
Date:	**2021-03-05**
Issued To:	**Bedfont Scientific Limited** **Station Road** **Harrietsham** **Maidstone** **Kent** **ME17 1JA** **United Kingdom**

Subcontractor:	**Service(s) supplied**
Stephen Rowe Cristimar E4-1 Avenida Juan Carlos I Los Cristianos, Arona, 38650 Santa Cruz De Tenerife Spain	**EU Representative**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 58024**
Date: **2021-03-05**
Issued To: **Bedfont Scientific Limited**
Station Road
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ME17 1JA
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Date	Reference Number	Action
08 March 2001		First issue
15 July 2005		Change to scope to remove 'development' and add 'ToxCo+'.
20 April 2006		Certificate renewal. Generalisation of scope to remove specific brand names. Extension of scope to include NO delivery systems
08 March 2011	7474996	Change of address from Laker Road, Rochester, to Station Road, Harrietsham. Certificate renewal
18 February 2016	8456499	Certificate renewal. Deletion of NO delivery systems from the scope of certificate. Addition of Subcontractor Integrated Technologies Limited, Ashford for Manufacture. Addition of Dongguan Approach Electronics and Plastic Manufacturing Factory for manufacture.
02 June 2016	8535196	Addition of NO delivery systems to the scope of certificate.
08 February 2019	7781630	Traceable to NB 0086.

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Date	Reference Number	Action
05 March 2021	3384427	Certificate renewal with the following changes. Removal of "NO delivery systems" from the scope of certificate. Addition of Device table. Addition of "Bedfont GmbH, Mitterbachweg 18, 5081 Anif, Austria" as EU Representative. Removal of Significant Sub-contractors "Dongguan Approach Electronics and Plastick Manufacturing Company, Xinxing Industrial Park, Wusha Management District, Chang'an Town, Dongguan, Guangdong, 523859, China and "Integrated Technologies Limited, Viking House, Ellingham Way, Ashford, Kent, TN23 6NF, United Kingdom".
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
20 July 2022	3661694	Change of EU representative from "Bedfont GmbH, Mitterbachweg 18, 5018 Anif , Austria" to "Stephen Rowe, Cristimar E4-1, Avenida Juan Carlos I, Los Cristianos, Arona, 38650, Santa Cruz De Tenerife, Spain.

Inspiring trust for a more resilient world.

20 July 2022

Bedfont Scientific Limited
Station Road
Harrietsham
Maidstone
Kent
ME17 1JA
United Kingdom

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	**Directive and Annex**	**Reference Number**	**Changes approved**
CE 58024	93/42/EEC Annex II excluding Section 4	3661694	Change of EU representative from "Bedfont GmbH, Mitterbachweg 18, 5018 Anif , Austria" to "Stephen Rowe, Cristimar E4-1, Avenida Juan Carlos I, Los Cristianos, Arona, 38650, Santa Cruz De Tenerife, Spain.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices