By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 01469**

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

In respect of:

Those aspects of Annex V related to metrology in the manufacture of breath gas monitors

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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: **1996-11-22** Date: **2021-05-19** Expiry Date: **2024-05-26**

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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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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Supplementary Information to CE 01469

Issued To:

Bedfont Scientific Limited
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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 1102	Breath gas monitors	N/A for Class Im

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Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

Certificate No:	**CE 01469**
Date:	**2021-05-19**
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 - Production Quality Assurance Certificate History

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Date	Reference Number	Action
22 November 1996		First issue
03 April 1997		Change of scope
16 April 1997		Change of scope
19 April 1999		Change of scope
14 July 1999		Change of scope
08 March 2001		Change of scope. Change of company address
14 January 2004		New certificate format and renewal
20 October 2006		Five years renewal
13 March 2009	7328585	Change of scope from 'Those aspects of Annex V related to the metrology in the manufacture of the Gastrolyzer' to 'Those aspects of Annex V related to the manufacture of breath gas monitors'
22 February 2011	7633318	Change of address from 105 Laker Road, Rochester Airport Industrial Estate, Rochester, Kent, ME1 3QX to Station Road, Harrietsham, Maidstone, Kent ME17 1JA, UK.
16 November 2011	7759880	Five years renewal
18 November 2016	8592827	Five years renewal
08 February 2019	7781630	Traceable to NB 0086.

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Date	Reference Number	Action
19 May 2021	3388840	Certificate renewal. Addition of device table. Addition of "Bedfont GmbH, Mitterbachweg 18, 5081 Anif, Austria" as EU Representative.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
20 July 2022	3663822	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." Typographical error noted in device table. Devices are Class Im, not Class IIa.

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.
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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 01469	93/42/EEC Annex V	3663822	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. Typographical error noted in device table. Devices are Class Im, not Class IIa

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

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780
info.nl@bsigroup.com bsigroup.nl

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SUSTAINABLE DEVELOPMENT GOALS