Pulmodyne, Inc
2055 Executive Drive
Indiana
46241
USA

28 July 2023

Notified Body Confirmation Letter
Reference: EU2023-607/661880

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:

Pulmodyne, Inc
2055 Executive Drive
Indiana
46241
USA

SRN Number (if available): Not Available

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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.,

Lizzy Szott

Digitally signed by Lizzy Szott
Date: 2023.07.28 10:01:56 -04'00'

Lizzy Szott

BSI Scheme Manager

bsi.

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
AccuPAP	Class IIa	N/A	CE 649013, BSI 2797
Control Cric	Class IIa	N/A	CE 649013, BSI 2797
Filters & HMEs	Class IIa	N/A	CE 649013, BSI 2797
Manual Resuscitators	Class IIa	N/A	CE 649013, BSI 2797
Nasal Masks	Class IIa	N/A	CE 649013, BSI 2797
Respiratory Face Masks & Accessories	Class IIa	N/A	CE 649013, BSI 2797
Patient Circuits	Class IIa	N/A	CE 649013, BSI 2797
O2 RESQ / O2-MAX	Class IIa	N/A	CE 649013, BSI 2797
Go-PAP	Class IIa	N/A	CE 649013, BSI 2797
Disposable Pressure Manometer	Class I device with a measuring function	N/A	CE 649013, BSI 2797
FENEM CO2 Indicator	Class I device with a measuring function	N/A	CE 649013, BSI 2797

Table 2: Devices covered by this letter and for which the NB is NOT 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
N/A	Choose an item.	N/A	N/A

Confirmation Letter Revision History

Date	Action
2023/07/28	Initial issue

EU MDR Article 120 extension confirmation

Manufacturer Name ('Manufacturer')	**Manufacturer Address**	**MHRA Account Number**
Pulmodyne, Inc.	2055 Executive Drive Indianapolis, Indiana 46241 USA	0000025819
UKRP/Northern Ireland Authorised Representative Name (if applicable)	**UKRP/NI Authorised Representative Address**	**MHRA Account Number**
Intersurgical Ltd.	Crane House Molly Millars Lane Wokingham Berkshire RG41 2RZ England, United Kingdom	0000009283

I/we declare that:

- the CE certificate(s) listed below were issued under the EU Medical Devices Directive (93/42/EEC) or under the EU Active Implantable Medical Devices Directive (90/385/EEC) on or after 25 May 2017 and were still valid on 26 May 2021 **AND**

- the conditions for extension of the validity of the CE certificate(s) (under the EU Medical Devices Regulation (2017/745) (EU MDR) Article 120) set out below have been met in relation to the CE certificates as listed in the table below

	CE Certificate number/s	Notified Body that issued the certificate	Expiry date/s	Notified Body currently responsible for surveillance	Extended validity date(s) for NI market	Extended validity date(s) for GB market
a) The CE certificate(s) **was due to expire on or after 20 March 2023**, and remains valid by virtue of EU MDR Article 120(2).	CE 649013	The BSI Group The Netherlands B.V. 2797	1 August 2023	The BSI Group The Netherlands B.V. 2797	31 December 2028	30 June 2028

Signed by Manufacturer:

Tamara Lefevers	Vice President, Regulatory Affairs & Quality Assurance	July 31, 2023
Name of Signatory	**Position of Signatory**	**Date**

Signed by UK Responsible Person/Northern Ireland Authorised Representative (if applicable):

Ivan Seniut	Group Quality & Regulatory Affairs Director	July 31, 2023
Name of Signatory	**Position of Signatory**	**Date**