

### EU MDR Article 120 extension confirmation

<b>Manufacturer Name ('Manufacturer')</b>	<b>Manufacturer Address</b>	<b>MHRA Account Number</b>
Pulmonary, Inc.	2055 Executive Drive Indianapolis, Indiana 46241 USA	0000025819
<b>UKRP/Northern Ireland Authorised Representative Name (if applicable)</b>	<b>UKRP/NI Authorised Representative Address</b>	<b>MHRA Account Number</b>
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) <b>was due to expire on or after 20 March 2023</b> , 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

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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

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Name of Signatory      Position of Signatory      Date

