

**DECLARATION OF CONFORMITY**  
**Medical Devices – VentiSure2 & VT Sure Resuscitators**

We hereby declare the distributed CE marked product specified in the annexed product list are covered by the "CE Marking of Conformity Certificate", reference number CE 649013, issued on June 14, 2016 and delivered by BSI, Notified Body Identification Number 2797, and conform to the required technical documentation, in accordance with Annex VII of the "EC- Directive", the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices, including all subsequent amendments.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class IIa, meet the provisions of the EC-Directive which apply to them.

This declaration is based on the application of the Quality System approved for the manufacture and final inspection of the products concerned, in accordance with Annex V of the EC-Directive. The conformity of the production quality assurance set out in the Annex V, is described in the said CE Marking of Conformity Certificate, issued and delivered by BSI.

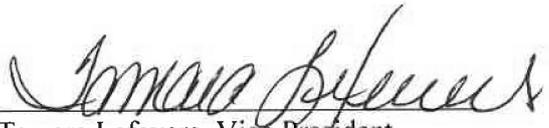
This declaration is supported by the Quality System certification based on the harmonized standards ISO 13485; 2016, Quality System Certificate with reference number F M 645459, issued on January 19, 2016 and delivered by BSI.

We declare the EC Representative for the product specified in the product list is QNET BV, Kantstraat 19, NL-5076 NP Haaren, The Netherlands.

This Declaration of Conformity covers the products as specified in the list belonging to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at the following site:

Pulmodyne, Inc.  
2055 Executive Drive  
Indianapolis, IN 46241 USA

Date: May 8, 2024



Tamara Lefevers, Vice President  
Regulatory Affairs & Quality Assurance

Annex: Product List (Rev C)

**VentiSure2 & VT Sure Resuscitators  
Product List – Rev C**

<u>Product Number</u>	<u>Description</u>	<u>1st CE Marked Lot</u>
7151111	BVM PAED 550ML BAG P/RELEASE 40SIZE 3 MASK	231101
7152111	BVM ADULT 1.5L BAG SIZE 5 MASK	231023
7153111	BVM SMALL ADULT/PAED 1L BAG P/RELEASE 40SIZE 4MASK	TBD
7154111	BVM PAED 550ML BAG P/RELEASE 40SIZE 1 MASK	231101
313-5582	Lg. Adult resus bag ORB	3135582100720
313-5581	Adult resus bag ORB	3135581100720
313-5580	Pediatric resus bag ORB, DPM	3135580100720
313-5579	Infant resus bag ORB, DPM	TBD
313-5680	Lg Adult resus bag w/ PEEP ORB	TBD
313-5679	Adult resus bag w/PEEP ORB	TBD
313-5678	Pediatric resus bag w/PEEP ORB, DPM	TBD
313-5677	Infant resus bag W/PEEP ORB, DPM	TBD
313-5688	Lg. Adult resus bag w/PEEP ORT	TBD
313-5687	Adult resus bag w/PEEP ORT	TBD
313-5686	Pediatric resus bag w/PEEP ORT DPM	TBD
313-5685	Infant resus bag w/PEEP ORT DPM	TBD
313-5734	Lg Adult resus bag ORT	TBD
313-5735	Adult resus bag ORT	TBD
313-5736	Pediatric resus bag ORT DPM	TBD
313-5737	Infant resus bag ORT DPM	TBD

313-5739	Lg Adult resus bag ORB 14' 02 Tube	TBD
313-5740	Adult resus bag ORB 14' 02 Tube	TBD
313-5741	Pediatric resus bag w/PEEP ORT	TBD
313-5726	Pediatric resus bag ORB DPM 3 MSK	TBD
313-5800	Pediatric resus bag ORT DPM PEEP	TBD
313-5801	Infant resus bag ORT DPM PEEP	TBD
313-5803	Adult resus bag ORT DPM	TBD
313-5804	Adult resus bag ORT Popoff	TBD
313-5810	Adult resus bag ORB DPM	TBD
313-5811	Lg Adult resus bag ORB	TBD
313-5812	Adult resus bag ORT PEEP	TBD
313-5813	Lg Adult resus bag ORT PEEP	TBD
313-5817	Infant resus bag ORB 14' 02 Tube, DPM	TBD
313-5818	Pediatric resus bag ORB	TBD
313-5849	Infant resus bag ORB PEEP DPM 2MSKS	TBD
313-5850	Pediatric resus bag ORB PEEP DPM 2MSKS	TBD
313-5851	Lg Adult resus bag ORB PEEP DPM	TBD
313-5911	Neo/Infant resus bag ORB DPM	TBD
313-5912	Neo/Infant resus bag ORB DPM PEEP	TBD
313-5948	Lg Adult resus bag ORB PEEP Lg Mask	TBD