



## DECLARATION OF CONFORMITY Medical Devices -DART

We hereby declare the distributed CE marked product specified in the annexed product list conform to the required technical documentation, in accordance with MDR 745/2017, concerning medical devices. In addition, we ensure and declare that the distributed CE marked products, specified in the annexed product list is a Class I device, meeting the provisions which apply to them.

This declaration, is issued under the sole responsibility of Pulmodyne, and based on the application of the Quality System approved for the manufacture and final inspection of the products concerned, in accordance with MDR 745/2017.

This declaration is supported by the Quality System certification based on the harmonized standards ISO 13485; 2016, Quality System Certificate with reference number FM 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, The Netherlands, SRN: NL-AR-000002695.

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  
SRN: US-MF-000017334

Date: April 19, 2022

Tamara Lefevers, Sr. QA/RA Manager

Annex: Product List Rev C

**Medical Devices -DART**

Rev C

<u>Product Number</u>	<u>Description</u>	<u>1st CE Marked Lot</u>	<u>Package Label</u>	<u>UDI-DI</u>	<u>Box Label</u>	<u>UDI-DI</u>
DART100	DART Nasal device w/3ml syringe	200818	4085	00841470100308	4086	10841470100305
DART110	DART Nasal device w/1ml syringe	201009	4584	00841470100292	4585	10841470100299
DART140	DART Nasal device w/3ml syringe, Vented Needle	210309	2915	00841470100674	2916	10841470100671
DART300	DART Nasal device w/o syringe	201009	4597	00841470100282	4598	10841470100282
REACH600	DART-Reach device w/5ml syringe	201002	4605	00841470100315	4606	10841470100312
REACH700	DART-Reach device (218 mm) w/o 5 ml syringe	201005	4607	00841470100322	4608	10841470100329
REACH720	DART-Reach device (117 mm) w/o 5 ml syringe	201005	4609	00841470100339	4610	10841470100336