

Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	Address	SRN
TyTek Medical	8904 Beckett Rd West Chester, OH 45069, US	US-MF-000032794

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Phone/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 EmergoEurope@ul.com

IMPORTER	
Name of Company	Address
MedEnvoy Global B.V.	WTC The Hauge Prinses Margrietplantsoen 33 Suite 123 2595 AM The Hauge, The Netherlands

PRODUCT IDENTIFICATION	
Product Name	Code / Catalog Number
PneumoDart	TM-317
Intended Purpose	Basic UDI-DI
PneumoDart is a compact, sterile, co-axial needle used to relieve a tension pneumothorax condition.	0855204008_PN_DARTGM

RISK CLASS FOR DEVICES		
Device Classification		Common Specifications / Standards
Class:	IIa	NA
Rule:	6	

NOTIFIED BODY			
Name of Company	ID Number	Conformity Assessment Procedure	Certificate Reference(s)
Intertek	2862	Annex IX Chapters I & III	28620166342

TyTek Medical declares that the above-mentioned products meet the provision of the following EU legislation:

- Medical Devices Regulation (EU) 2017/745

COMPANY REPRESENTATIVE: Mark Sweatman

TITLE: Technical Director / Management Representative

PLACE: West Chester, OH, US

SIGNATURE:

DATE: Jan 29-2024