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**
TPAK / TPAK10	TM-303 / TM-310
Intended Purpose	**Basic UDI-DI**
TPAK is a compact, sterile, catheter with needle introducer used to relieve a tension pneumothorax condition.	0855204008_TPAK_10B2

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

Digitally signed by Mark Sweatman
Date: 2024.01.29 10:52:22 -05'00'

TITLE: Technical Director / Management Representative
PLACE: West Chester, OH, US

SIGNATURE:
DATE: Jan 29, 2024