

Declaration of Conformity


Self Certify

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

MANUFACTURER		
Name of Company	Address	SRN
TyTek Medical Inc.	4700 Ashwood Dr., Suite 445 Cincinnati, OH 45241	TBD

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Telephone/fax/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone 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	Product Code / Catalog Number	Basic UDI-DI
TVAC	TM -909	0855204008_TVACSUC7R
Intended Purpose	Photo	
Manual Suction used for clearing upper airway.		

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	Common Specifications
Class 1, Non-Sterile Rule 5, Transient use	

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

- Medical Devices Regulation (EU) 2017/745
- List other EU legislation/Directives as applicable (delete this bullet if not applicable)

COMPANY REPRESENTATIVE: Mark Sweatman

TITLE: Management Representative

SIGNATURE:

PLACE: Cincinnati, OH, USA

DATE: Apr 25, 2022