Declaration of Conformity

(Notified Body Certified)

Rev 8

PRODUCT IDENTIFICATION	
Product name	**Model/number**
TPAK- 14g Chest Decompression Needle	TM-303

MANUFACTURER		
Name of company	**Address**	**Representative**
TyTek Medical, Inc.	4700 Ashwood Dr. Suite 445 Cincinnati, OH 45241 USA	Mark Sweatman

AUTHORIZED REPRESENTATIVE		
Name of company	**Address**	**Telephone/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com

REGISTRATION INFORMATION	
Notified Body and ID #	**CE certificate number**
NB1639 SGS House Noorderlaan 87 Antwerp, 2030 Belgium	US 19/819943610

CONFORMITY ASSESSMENT		
Device classification	**Route to compliance**	**Standards applied**
Class IIa Rule 5	Annex II of MDD 93/42/EEC Council Directive	ISO 13485 (current revisión) MDD 93/42/EEC

TyTek Medical declares that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices and Directive 93/42/EEC as transposed in the national laws of the Member States.

COMPANY REPRESENTATIVE: Mark Sweatman

TITLE: Management Representative **SIGNATURE:**

DATE: European format 29/06/2020