

## DECLARATION OF CONFORMITY

**Manufacturer:** DÖRT-A TIP MALZEMELERİ SAN. İTH. İHR. TİC. LTD. ŞTİ.  
**Address:** Balıkhisar Mahallesi Köyiçi Serpmeleri No: 795/A Akyurt / Ankara Turkey  
**Brand Name:** *4a-Medical*  
**Product Name:** *PVC Thorax Drain* x-ray line  
**Product Code:** **4APVC-TRX**  
**Product Models:** See ANNEX.

**Applicable directives:** 93/42/EEC Medical Devices Directives, Attachment II Except Clause 4 (Class IIa)  
**Classification:** Class IIa, Rule 7, Attachment IX  
**GMDN No:** 11305

**Applicable Directives:** TS EN 14971:2019, EN 24971:2020, TS EN 20697 : 2018, **EN ISO 15223-1:2021**, ISO 9001:2015, ISO 13485:2016, TS EN 20417:2021, TS EN ISO 14644-1:2016, TS EN ISO 14644-2:2016, TS EN ISO 14644-3:2019, TS EN ISO 14644-4:2006, TS EN ISO 14644-5:2006, **TS EN ISO 10993-12:2021**, TS ISO 11135:2014, TS EN ISO 14937:2011, TS ISO 11607-1:2020, TS EN ISO 11607-2:2020, TS EN ISO 17141:2020, TS EN ISO 11737-2:2020, TS EN ISO 10993-3:2015, TS EN ISO 10993-4:2020, TS EN ISO 10993-5:2010, TS EN ISO 10993-7:2010, TS EN ISO 10993-10:2014, TS EN ISO 10993-11:2018, TS EN ISO 10993-1:2020

**Certified body:** UDEM International Certification Auditing Training Center Industry And Trade Inc. Co.  
**Certified body address:** Mutlukent Mahallesi 2073.Sokak(Eski 93 Sokak) No:10 Çankaya-Ankara-Turkey  
**Descriptive number:** 2292  
**Certificate No:** M.2016.106.7276  
**First CE mark:** 31.07.2012  
**Certificate Expiry Date:** 27.05.2024

We DÖRT-A TIP MALZEMELERİ SAN. İTH. İHR. TİC. LTD. ŞTİ. declare that above mentioned product is fulfilling all legislation provisions in 93/42/EEC provision. We are conserving all corroborative documents in our own facility.  
**Place, Issue date:** Ankara, 12.01.2022

Canan ÖKTEM, General Manager  
Signature & Stamp

**4a medical** Dört -A Tıp Malzemeleri  
producing health for the world Sanayi İth. İhr. Tic. Ltd. Şti.  
Balıkhisar Mahallesi Köyiçi Serpmeleri No: 795/A  
Akyurt - ANKARA  
Tel: 0312 363 50 52-53 Fax: 0312 363 52 10  
Güdümlü Vergi Dairesi: 313 006 8000 / Akyurt - Ankara / Türkiye  
http://www.4amedical.com • ankara@4amedical.com  
Mersis No: 0313 0068 0000 0018

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**Dört-A Tıp Malzemeleri  
Sanayi İth. İhr. Tic. Ltd. Şti.**

ADRES : Balıkhisar Mah. Köyü Serpmeleri No: 795 / A  
Akyurt - ANKARA / TÜRKİYE

TEL : 0312.363 50 52-53

FAX : 0312.363 52 10

WEB : <http://www.4amedical.com>

E-MAIL : [ankara@4amedical.com](mailto:ankara@4amedical.com)

**ANNEX:**

PRODUCT	SIZE	INNER DIAMETER	OUTER DIAMETER	DIAMETER TOLERANCE	HOSE LENGTH	LENGTH OF TOLERANCE
PVC THORAX DRAIN	<b>16F</b>	2,80mm	5,33mm	$\pm 1,2mm$	52CM	$\pm 2CM$
PVC THORAX DRAIN	<b>18F</b>	3,40mm	6mm	$\pm 1,2mm$	52CM	$\pm 2CM$
PVC THORAX DRAIN	<b>20F</b>	3,45mm	6,66mm	$\pm 1,2mm$	52CM	$\pm 2CM$
PVC THORAX DRAIN	<b>22F</b>	4,10mm	7,33mm	$\pm 1,2mm$	52CM	$\pm 2CM$
PVC THORAX DRAIN	<b>24F</b>	5,45mm	8mm	$\pm 1,2mm$	52CM	$\pm 2CM$
PVC THORAX DRAIN	<b>26F</b>	5,75mm	8,66mm	$\pm 1,2mm$	52CM	$\pm 2CM$
PVC THORAX DRAIN	<b>28F</b>	5,95mm	9,33mm	$\pm 1,2mm$	52CM	$\pm 2CM$
PVC THORAX DRAIN	<b>30F</b>	6,80mm	10mm	$\pm 1,2mm$	52CM	$\pm 2CM$
PVC THORAX DRAIN	<b>32F</b>	7,50mm	10,66mm	$\pm 1,2mm$	52CM	$\pm 2CM$
PVC THORAX DRAIN	<b>34F</b>	8,10mm	11,33mm	$\pm 1,2mm$	52CM	$\pm 2CM$
PVC THORAX DRAIN	<b>36F</b>	9,75mm	12mm	$\pm 1,2mm$	52CM	$\pm 2CM$

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<b>REVISION HISTORY</b>		
<b>Rev. No:</b>	<b>Rev. Date:</b>	<b>Rev. Reason</b>
04	09.10.2019	<i>Revision history page has been added and the changes made are indicated in italics.</i>
05	30.09.2020	Standards have been checked.
06	26.07.2021	Standards have been checked.
07	16.08.2021	The document validity period has been changed.
08	03.11.2021	Brand name and product name revised
<b>09</b>	<b>12.01.2022</b>	<b><i>Product codes have been added and standards have been checked.</i></b>