

DECLARATION OF CONFORMITY

Manufacturer: DÖRT-A TIP MALZEMELERİ SAN. İTH. İHR. TİC. LTD. ŞTİ.
Address: Balıkhisar Mahallesi Köyiçi Serpmeleri No: 795/A Akyurt / Ankara
Brand Name: *4a-Medical*
Product Name: Silicone Thorax Drain – x-ray line
Product Code: 4ATRX
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 Standards: 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

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ANNEX:

PRODUCT	SIZE	INNER DIAMETER	OUTER DIAMETER	DIAMETER TOLERANCE	HOSE LENGTH	LENGTH TOLERANCE
<i>SILICONE THORAX DRAIN</i>	<i>9F</i>	<i>1,8 mm</i>	<i>3 mm</i>	<i>± 0,15 MM</i>	<i>50CM</i>	<i>± 2CM</i>
<i>SILICONE THORAX DRAIN</i>	<i>12F</i>	<i>2,5 mm</i>	<i>4 mm</i>	<i>± 0,2 MM</i>	<i>50CM</i>	<i>± 2CM</i>
<i>SILICONE THORAX DRAIN</i>	<i>15F</i>	<i>3,3 mm</i>	<i>5 mm</i>	<i>± 0,25 MM</i>	<i>50CM</i>	<i>± 2CM</i>
<i>SILICONE THORAX DRAIN</i>	<i>16F</i>	<i>3,5 mm</i>	<i>5,3 mm</i>	<i>± 0,26 MM</i>	<i>50CM</i>	<i>± 2CM</i>
<i>SILICONE THORAX DRAIN</i>	<i>18F</i>	<i>4 mm</i>	<i>6 mm</i>	<i>± 0,3 MM</i>	<i>50CM</i>	<i>± 2CM</i>
<i>SILICONE THORAX DRAIN</i>	<i>20F</i>	<i>4,5 mm</i>	<i>6,7 mm</i>	<i>± 0,33 MM</i>	<i>50CM</i>	<i>± 2CM</i>
<i>SILICONE THORAX DRAIN</i>	<i>21F</i>	<i>4,8 mm</i>	<i>7 mm</i>	<i>± 0,35 MM</i>	<i>50CM</i>	<i>± 2CM</i>
<i>SILICONE THORAX DRAIN</i>	<i>22F</i>	<i>5 mm</i>	<i>7,3 mm</i>	<i>± 0,36 MM</i>	<i>50CM</i>	<i>± 2CM</i>
<i>SILICONE THORAX DRAIN</i>	<i>24F</i>	<i>5,5 mm</i>	<i>8 mm</i>	<i>± 0,4 MM</i>	<i>50CM</i>	<i>± 2CM</i>
<i>SILICONE THORAX DRAIN</i>	<i>26F</i>	<i>5,7 mm</i>	<i>8,7 mm</i>	<i>± 0,43 MM</i>	<i>50CM</i>	<i>± 2CM</i>
<i>SILICONE THORAX DRAIN</i>	<i>27F</i>	<i>6,3 mm</i>	<i>9 mm</i>	<i>± 0,45 MM</i>	<i>50CM</i>	<i>± 2CM</i>
<i>SILICONE THORAX DRAIN</i>	<i>28F</i>	<i>6,5 mm</i>	<i>9,3 mm</i>	<i>± 0,46 MM</i>	<i>50CM</i>	<i>± 2CM</i>
<i>SILICONE THORAX DRAIN</i>	<i>30F</i>	<i>7 mm</i>	<i>10 mm</i>	<i>± 0,5 MM</i>	<i>50CM</i>	<i>± 2CM</i>
<i>SILICONE THORAX DRAIN</i>	<i>32F</i>	<i>7,5 mm</i>	<i>10,7 mm</i>	<i>± 0,53 MM</i>	<i>50CM</i>	<i>± 2CM</i>
<i>SILICONE THORAX DRAIN</i>	<i>33F</i>	<i>7,8 mm</i>	<i>11 mm</i>	<i>± 0,55 MM</i>	<i>50CM</i>	<i>± 2CM</i>
<i>SILICONE THORAX DRAIN</i>	<i>36F</i>	<i>8,5 mm</i>	<i>12 mm</i>	<i>± 0,6 MM</i>	<i>50CM</i>	<i>± 2CM</i>
<i>SILICONE THORAX DRAIN</i>	<i>40F</i>	<i>9,5 mm</i>	<i>13,3 mm</i>	<i>0,66 MM</i>	<i>50CM</i>	<i>± 2CM</i>

REVISION HISTORY		
Rev. No:	Rev. Date:	Rev. Reason
<i>03</i>	<i>09.10.2019</i>	<i>Revision history page has been added and the changes made are indicated in italics.</i>
04	30.09.2020	Standards have been checked.
05	16.08.2021	Standards have been checked.
06	<i>03.11.2021</i>	The brand name and product name have been revised. Details added to the table.
<i>07</i>	<i>12.01.2022</i>	<i>Product codes have been added and standards have been checked.</i>