

## 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:** Dört-A Medical  
**Product Name:** Polypropylene Mesh  
**Product Code:** 4APPM  
**Product Models:** See ANNEX.

**Applicable directives:** 93/42/EEC Medical Devices Directives, Attachment II Except Clause 4 (Class IIb)  
**Classification:** Class IIb, Rule 9, Attachment IX  
**GMDN No:** 44681

**Applicable Standards:** TS EN 14971:2019, EN 24971:2020, **EN ISO 15223:2021**, 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, EN ISO 17141:2020, EN ISO 10993-4:2020, EN ISO 10993-5:2010, EN ISO 10993-7:2010, EN ISO 10993-10:2014, **EN ISO 10993-11:2018**, EN ISO 10993-18:2020, EN ISO 10993-1:2020, EN ISO 10993-3:2015

**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



## **ANNEX**

<b>TYPE OF MATERIAL</b>
<b>POLYPROPYLENE MESH 6X11</b>
<b>POLYPROPYLENE MESH 7,5X15</b>
<b>POLYPROPYLENE MESH 8X10</b>
<b>POLYPROPYLENE MESH 10X15</b>
<b>POLYPROPYLENE MESH 10X20</b>
<b>POLYPROPYLENE MESH 15X15</b>
<b>POLYPROPYLENE MESH 15X20</b>
<b>POLYPROPYLENE MESH 20X20</b>
<b>POLYPROPYLENE MESH 20X30</b>
<b>POLYPROPYLENE MESH 30X30</b>

<b>REVISION HISTORY</b>		
<b>Rev. No:</b>	<b>Rev. Date:</b>	<b>Rev. Reason</b>
03	19.08.2020	Revision history page has been added and the changes made are indicated in italics. The standards have been updated.
04	19.01.2021	Standard checks have been done The TS EN 14698 standard has been removed because it was canceled.
05	16.08.2021	Standards have been reviewed.
<b>06</b>	<b>12.01.2022</b>	<b><i>Product codes have been added and standards have been reviewed.</i></b>