

## 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:** Channel Drain Normal/ x-ray line/ (Flat/round)  
**Product Code:** 4ARCHD

### PRODUCT MODELS:

**ROUND CHANNEL FLAT DRAIN 3 MM**  
**ROUND CHANNEL FLAT DRAIN 5 MM**  
**ROUND CHANNEL FLAT DRAIN 7 MM**  
**ROUND CHANNEL FLAT DRAIN 10 MM**

**Applicable directives:** 93/42/EEC COUNCIL DIRECTIVE, Except for Supplement II Article 4 ( Class IIa)  
**Classification:** Class IIa, Rule 7, Attachment IX  
**GMDN No:** 11305

**Applicable Standarts:** 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 10993-1:2020, 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

**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

Doc. No.: 4A-FR-193  
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Rev. Date / No.: 16.08.2021/ 07



<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	19.08.2020	Standard checks were made.
06	04.12.2020	Based on the 2020 Udem audit nonconformity, the names in the declaration of conformity have been changed to be the same as the product descriptions.
07	16.08.2021	Standard checks were made.
08	12.01.2022	<i>Product codes have been added and standard dates have been updated.</i>