

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: Flat Drain – Normal / x-ray line
Product Code: 4AFD
Product Models: *SILICONE FLAT DRAIN 5 MM*
SILICONE FLAT DRAIN 7 MM
SILICONE FLAT DRAIN 10 MM
SILICONE FLAT DRAIN 13 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 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 Türkiye
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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<i>REVISION HISTORY</i>		
<i>Rev. No:</i>	<i>Rev. Date:</i>	<i>Rev. Reason</i>
<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	28.07.2020	Standards updated
05	16.08.2021	Standards updated. The document validity date has been updated.
<i>06</i>	<i>12.01.2022</i>	<i>Product codes have been added and standard dates have been updated.</i>