

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: Silicone Redon Drain – blue x-ray line
Product Code: 4ASRD
Product Models: See ANNEX.
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 15223-1:2016, 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 10993-12:2013, 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



<i>PRODUCT (SILICON)</i>	<i>SIZE</i>
HEMOWAK REDON DRAIN	10F
HEMOWAK REDON DRAIN	12F
HEMOWAK REDON DRAIN	14F
HEMOWAK REDON DRAIN	16F

<i>REVISION HISTORY</i>		
<i>Rev. No:</i>	<i>Rev. Date:</i>	<i>Rev. Reason</i>
07	16.08.2021	Standard checks were made. Certificate validity date has been updated.
08	12.01.2022	<i>Product codes have been added and standard checks were made.</i>