

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: PVC Redon Drain – x-ray line
Product Code: 4APVC-RD
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 ISO 14971:2019, TS EN ISO 24971:2020, **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 10993-1:2020, 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 20697:2018

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

4a medical Dört-A Tıp Malzemeleri
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Publishing date: 10.07.2015
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ANNEX:

<i>PRODUCT (PVC)</i>	<i>SIZE</i>
HEMOWAK REDON DRAIN	8F
HEMOWAK REDON DRAIN	10F
HEMOWAK REDON DRAIN	12F
HEMOWAK REDON DRAIN	14F
HEMOWAK REDON DRAIN	16F
HEMOWAK REDON DRAIN	18F

REVISION HISTORY		
Rev. No:	Rev. Date:	Rev. Reason
03	09.10.2019	<i>Revision history page has been added and the changes made are indicated in italics.</i>
04	01.10.2020	Review process has been done
05	16.08.2021	Review process has been done
06	12.01.2022	<i>Product codes have been added and standard dates have been updated.</i>