

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 STRAIGHT DRAIN Normal /x-ray line /
Product code: 4APVC-SD
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.
Product Models: *See the Annex.*

Applicable Standards: EN 14971:2019, EN 24971:2020, TS EN 20697 : 2018, **EN ISO 15223-1:2021**, ISO 9001:2015, ISO 13485:2016, TS EN ISO 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 Turkiye

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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Mersis No: 0313 0000 0000 0018

ANNEX:

PRODUCT	SIZE
PVC STRAIGHT DRAIN 50CM-90CM-100CM WITH BAG/WITHOUT BAG (SOFT DRAIN)	10F
PVC STRAIGHT DRAIN 50CM-90CM-100CM WITH BAG/WITHOUT BAG (SOFT DRAIN)	12F
PVC STRAIGHT DRAIN 50CM-90CM-100CM WITH BAG/WITHOUT BAG (SOFT DRAIN)	14F
PVC STRAIGHT DRAIN 50CM-90CM-100CM WITH BAG/WITHOUT BAG (SOFT DRAIN)	15F
PVC STRAIGHT DRAIN 50CM-90CM-100CM WITH BAG/WITHOUT BAG (SOFT DRAIN)	16F
PVC STRAIGHT DRAIN 50CM-90CM-100CM WITH BAG/WITHOUT BAG (SOFT DRAIN)	18F
PVC STRAIGHT DRAIN 50CM-90CM-100CM WITH BAG/WITHOUT BAG (SOFT DRAIN)	20F
PVC STRAIGHT DRAIN 50CM-90CM-100CM WITH BAG/WITHOUT BAG (SOFT DRAIN)	21F
PVC STRAIGHT DRAIN 50CM-90CM-100CM WITH BAG/WITHOUT BAG (SOFT DRAIN)	22F
PVC STRAIGHT DRAIN 50CM-90CM-100CM WITH BAG/WITHOUT BAG (SOFT DRAIN)	24F
PVC STRAIGHT DRAIN 50CM-90CM-100CM WITH BAG/WITHOUT BAG (SOFT DRAIN)	26F
PVC STRAIGHT DRAIN 50CM-90CM-100CM WITH BAG/WITHOUT BAG (SOFT DRAIN)	27F
PVC STRAIGHT DRAIN 50CM-90CM-100CM WITH BAG/WITHOUT BAG (SOFT DRAIN)	28F
PVC STRAIGHT DRAIN 50CM-90CM-100CM WITH BAG/WITHOUT BAG (SOFT DRAIN)	30F
PVC STRAIGHT DRAIN 50CM-90CM-100CM WITH BAG/WITHOUT BAG (SOFT DRAIN)	32F
PVC STRAIGHT DRAIN 50CM-90CM-100CM WITH BAG/WITHOUT BAG (SOFT DRAIN)	33F

<i>PVC STRAIGHT DRAIN 50CM-90CM-100CM WITH BAG/WITHOUT BAG (SOFT DRAIN)</i>	<i>34F</i>
<i>PVC STRAIGHT DRAIN 50CM-90CM-100CM WITH BAG/WITHOUT BAG (SOFT DRAIN)</i>	<i>36F</i>
<i>PVC STRAIGHT DRAIN 50CM-90CM-100CM WITH BAG/WITHOUT BAG (SOFT DRAIN)</i>	<i>40 F</i>

REVISION HISTORY		
<i>Rev. No:</i>	<i>Rev. Date:</i>	<i>Rev. Reason</i>
<i>04</i>	<i>09.10.2019</i>	<i>Revision history page has been added and the changes made are indicated in italics.</i>
05	12.02.2020	Different sizes bolded, measurement information has been added.
06	16.06.2020	The dates of applicable standards have been reviewed.
07	29.09.2020	English expressions have been removed.
08	01.10.2020	24971 standard added
09	24.02.2021	The dates of applicable standards have been reviewed.
10	16.08.2021	Applicable standards were reviewed.
<i>11</i>	<i>12.01.2022</i>	<i>Product codes have been added and standard dates have been updated.</i>