

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 Straight Dren - Normal /x-ray line
Product Code: 4ASSD
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: 11301

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

Doc. No.: 4A-FR-200
Publishing date: 10.07.2015
Rev. Date / No.: 16.08.2021/ 08



ANNEX:

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

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

<i>REVISION HISTORY</i>		
<i>Rev. No</i>	<i>Rev. Date:</i>	<i>Rev. Reason</i>
03	09.10.2019	<i>Revision history page has been added and the changes made are indicated in italics.</i>
04	12.02.2020	Different sizes bolded, measurement information has been added.
05	16.06.2020	The dates of applicable standards have been reviewed.
06	29.09.2020	English expressions have been removed.
07	01.10.2020	Standard dates have been updated.
08	16.08.2021	Standards have been reviewed.
09	12.01.2022	<i>Product codes have been added and standards have been reviewed.</i>