

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 Penrose Drain – (blue x-ray line)
Product Code: 4APD
Product Models: See ANNEX.

Applicable directives: 93/42/EEC COUNCIL DIRECTIVE, Except for Supplement II Article 4 (Class IIa)
(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-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. ŞTİ. are in full compliance with all legislation provisions in 93/42/EEC provision. We are

Place & Issue Date: Ankara, 12.01.2022

4a medical Dört -A Tıp Malzemeleri
producing health for the world Sanayi İth. İhr. Tic. Ltd. Şti.
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Mersis No: 0313 0066 0600 0018

Canan OKTEM, General Manager

Signature & Stamp

med product is fulfilling
requirements in our own facility.

ANNEX

SILICONE PernoSE DRAIN MATERIAL TYPES

SILICONE PernoSE DRAIN 6MM

SILICONE PernoSE DRAIN 8MM

SILICONE PernoSE DRAIN 10MM

SILICONE PernoSE DRAIN 12MM

| REVISION HISTORY | | |
|-------------------------|-------------------|--|
| Rev. No: | Rev. Date: | Rev. Reason |
| 05 | 30.09.2020 | Revision history page has been added and the changes made are indicated in italics. |
| 06 | 04.12.2020 | Based on the 2020 Udem audit nonconformity, the names in the declaration of conformity have been changed to be the same as the product descriptions. |
| 07 | 16.08.2021 | Standards have been reviewed. |
| 08 | 12.01.2022 | <i>Product codes have been added and standards have been reviewed.</i> |