

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 Hemovac Drain
Product Code: 4ASHD
Drain Set (Single / Double)
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: 35824

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, TS EN 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-202
Publishing date: 10.07.2015
Rev. Date / No.: 16.08.2021/05

ANNEX:

- ✓ **SILICONE HEMOVAC DRAIN 400 CC GUSSET RESERVOIR 10F SINGLE**
- ✓ **SILICONE HEMOVAC DRAIN 400 CC GUSSET RESERVOIR 10F DOUBLE**
- ✓ **SILICONE HEMOVAC DRAIN 400 CC GUSSET RESERVOIR 12F SINGLE**
- ✓ **SILICONE HEMOVAC DRAIN 400 CC GUSSET RESERVOIR 12F DOUBLE**
- ✓ **SILICONE HEMOVAC DRAIN 400 CC GUSSET RESERVOIR 14F DOUBLE**
- ✓ **SILICONE HEMOVAC DRAIN 400 CC GUSSET RESERVOIR 14F DOUBLE**
- ✓ **SILICONE HEMOVAC DRAIN 400 CC GUSSET RESERVOIR 16F SINGLE**
- ✓ **SILICONE HEMOVAC DRAIN 400 CC GUSSET RESERVOIR 16F DOUBLE**

- ✓ **SILICONE HEMOVAC DRAIN 200 CC GUSSET RESERVOIR 10F SINGLE**
- ✓ **SILICONE HEMOVAC DRAIN 200 CC GUSSET RESERVOIR 10F DOUBLE**
- ✓ **SILICONE HEMOVAC DRAIN 200 CC GUSSET RESERVOIR 12F SINGLE**
- ✓ **SILICONE HEMOVAC DRAIN 200 CC GUSSET RESERVOIR 12F DOUBLE**
- ✓ **SILICONE HEMOVAC DRAIN 200 CC GUSSET RESERVOIR 14F SINGLE**
- ✓ **SILICONE HEMOVAC DRAIN 200 CC GUSSET RESERVOIR 14F DOUBLE**
- ✓ **SILICONE HEMOVAC DRAIN 200 CC GUSSET RESERVOIR 16F SINGLE**
- ✓ **SILICONE HEMOVAC DRAIN 200 CC GUSSET RESERVOIR 16F DOUBLE**

- ✓ **SILICONE HEMOVAC DRAIN 125 CC BOMBA RESERVOIR 10F SINGLE**
- ✓ **SILICONE HEMOVAC DRAIN 125 CC BOMBA RESERVOIR 10F DOUBLE**
- ✓ **SILICONE HEMOVAC DRAIN 125 CC BOMBA RESERVOIR 12F SINGLE**
- ✓ **SILICONE HEMOVAC DRAIN 125 CC BOMBA RESERVOIR 12F DOUBLE**
- ✓ **SILICONE HEMOVAC DRAIN 125 CC BOMBA RESERVOIR 14F SINGLE**
- ✓ **SILICONE HEMOVAC DRAIN 125 CC BOMBA RESERVOIR 14F DOUBLE**
- ✓ **SILICONE HEMOVAC DRAIN 125 CC BOMBA RESERVOIR 16F SINGLE**
- ✓ **SILICONE HEMOVAC DRAIN 125 CC BOMBA RESERVOIR 16F DOUBLE**

- ✓ **SILICONE HEMOVAC DRAIN 200 CC BOMBA RESERVOIR 10F SINGLE**
- ✓ **SILICONE HEMOVAC DRAIN 200 CC BOMBA RESERVOIR 10F DOUBLE**
- ✓ **SILICONE HEMOVAC DRAIN 200 CC BOMBA RESERVOIR 12F SINGLE**
- ✓ **SILICONE HEMOVAC DRAIN 200 CC BOMBA RESERVOIR 12F DOUBLE**
- ✓ **SILICONE HEMOVAC DRAIN 200 CC BOMBA RESERVOIR 14F SINGLE**
- ✓ **SILICONE HEMOVAC DRAIN 200 CC BOMBA RESERVOIR 14F DOUBLE**

- ✓ **SILICONE HEMOVAC DRAIN 200 CC BOMBA RESERVOIR 16F SINGLE**
- ✓ **SILICONE HEMOVAC DRAIN 200 CC BOMBA RESERVOIR 16F DOUBLE**

- ✓ **SILICONE HEMOVAC DRAIN 250 CC BOMBA RESERVOIR 10F SINGLE**
- ✓ **SILICONE HEMOVAC DRAIN 250 CC BOMBA RESERVOIR 10F DOUBLE**
- ✓ **SILICONE HEMOVAC DRAIN 250 CC BOMBA RESERVOIR 12F SINGLE**
- ✓ **SILICONE HEMOVAC DRAIN 250 CC BOMBA RESERVOIR 12F DOUBLE**
- ✓ **SILICONE HEMOVAC DRAIN 250 CC BOMBA RESERVOIR 14F SINGLE**
- ✓ **SILICONE HEMOVAC DRAIN 250 CC BOMBA RESERVOIR 14F DOUBLE**
- ✓ **SILICONE HEMOVAC DRAIN 250 CC BOMBA RESERVOIR 16F SINGLE**
- ✓ **SILICONE HEMOVAC DRAIN 250 CC BOMBA RESERVOIR 16F DOUBLE**

- ✓ **SILICONE HEMOVAC DRAIN 400 CC BOMBA RESERVOIR 10F SINGLE**
- ✓ **SILICONE HEMOVAC DRAIN 400 CC BOMBA RESERVOIR 10F DOUBLE**
- ✓ **SILICONE HEMOVAC DRAIN 400 CC BOMBA RESERVOIR 12F SINGLE**
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- ✓ **SILICONE HEMOVAC DRAIN 400 CC BOMBA RESERVOIR 16F SINGLE**
- ✓ **SILICONE HEMOVAC DRAIN 400 CC BOMBA RESERVOIR 16F DOUBLE**

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	28.04.2021	Standard dates have been checked.
05	16.08.2021	Standard dates have been checked.
06	12.01.2022	<i>Product codes have been added and standard dates have been updated.</i>