

## 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 Hemovac Drain Set (Single/Double)  
**Product Code:** 4AHD  
**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

**4a medical** Dört -A Tıp Malzemeleri  
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**ANNEX:**

*PVC HEMOVAC DRAIN 400 CC GUSSET RESERVOIR 10F SINGLE*  
*PVC HEMOVAC DRAIN 400 CC GUSSET RESERVOIR 10F DOUBLE*  
*PVC HEMOVAC DRAIN 400 CC GUSSET RESERVOIR 12F SINGLE*  
*PVC HEMOVAC DRAIN 400 CC GUSSET RESERVOIR 12F DOUBLE*  
*PVC HEMOVAC DRAIN 400 CC GUSSET RESERVOIR 14F SINGLE*  
*PVC HEMOVAC DRAIN 400 CC GUSSET RESERVOIR 14F DOUBLE*  
*PVC HEMOVAC DRAIN 400 CC GUSSET RESERVOIR 16F SINGLE*  
*PVC HEMOVAC DRAIN 400 CC GUSSET RESERVOIR 16F DOUBLE*  
*PVC HEMOVAC DRAIN 400 CC GUSSET RESERVOIR 18F SINGLE*  
*PVC HEMOVAC DRAIN 400 CC GUSSET RESERVOIR 18F DOUBLE*

*PVC HEMOVAC DRAIN 200 CC GUSSET RESERVOIR 10F SINGLE*  
*PVC HEMOVAC DRAIN 200 CC GUSSET RESERVOIR 10F DOUBLE*  
*PVC HEMOVAC DRAIN 200 CC GUSSET RESERVOIR 12F SINGLE*  
*PVC HEMOVAC DRAIN 200 CC GUSSET RESERVOIR 12F DOUBLE*  
*PVC HEMOVAC DRAIN 200 CC GUSSET RESERVOIR 14F SINGLE*  
*PVC HEMOVAC DRAIN 200 CC GUSSET RESERVOIR 14F DOUBLE*  
*PVC HEMOVAC DRAIN 200 CC GUSSET RESERVOIR 16F SINGLE*  
*PVC HEMOVAC DRAIN 200 CC GUSSET RESERVOIR 16F DOUBLE*  
*PVC HEMOVAC DRAIN 200 CC GUSSET RESERVOIR 18F SINGLE*  
*PVC HEMOVAC DRAIN 200 CC GUSSET RESERVOIR 18F DOUBLE*

*PVC HEMOVAC DRAIN 125 CC BOMBA RESERVOIR 10F SINGLE*  
*PVC HEMOVAC DRAIN 125 CC BOMBA RESERVOIR 10F DOUBLE*  
*PVC HEMOVAC DRAIN 125 CC BOMBA RESERVOIR 12F SINGLE*  
*PVC HEMOVAC DRAIN 125 CC BOMBA RESERVOIR 12F DOUBLE*  
*PVC HEMOVAC DRAIN 125 CC BOMBA RESERVOIR 14F SINGLE*  
*PVC HEMOVAC DRAIN 125 CC BOMBA RESERVOIR 14F DOUBLE*  
*PVC HEMOVAC DRAIN 125 CC BOMBA RESERVOIR 16F SINGLE*  
*PVC HEMOVAC DRAIN 125 CC BOMBA RESERVOIR 16F DOUBLE*  
*PVC HEMOVAC DRAIN 125 CC BOMBA RESERVOIR 18F SINGLE*  
*PVC HEMOVAC DRAIN 125 CC BOMBA RESERVOIR 18F DOUBLE*

*PVC HEMOVAC DRAIN 200 CC BOMBA RESERVOIR 10F SINGLE*  
*PVC HEMOVAC DRAIN 200 CC BOMBA RESERVOIR 10F DOUBLE*

***PVC HEMOVAC DRAIN 200 CC BOMBA RESERVOIR 12F SINGLE***  
***PVC HEMOVAC DRAIN 200 CC BOMBA RESERVOIR 12F DOUBLE***  
***PVC HEMOVAC DRAIN 200 CC BOMBA RESERVOIR 14F SINGLE***  
***PVC HEMOVAC DRAIN 200 CC BOMBA RESERVOIR 14F DOUBLE***  
***PVC HEMOVAC DRAIN 200 CC BOMBA RESERVOIR 16F SINGLE***  
***PVC HEMOVAC DRAIN 200 CC BOMBA RESERVOIR 16F DOUBLE***  
***PVC HEMOVAC DRAIN 200 CC BOMBA RESERVOIR 18F SINGLE***  
***PVC HEMOVAC DRAIN 200 CC BOMBA RESERVOIR 18F DOUBLE***

***PVC HEMOVAC DRAIN 250 CC BOMBA RESERVOIR 10F SINGLE***  
***PVC HEMOVAC DRAIN 250 CC BOMBA RESERVOIR 10F DOUBLE***  
***PVC HEMOVAC DRAIN 250 CC BOMBA RESERVOIR 12F SINGLE***  
***PVC HEMOVAC DRAIN 250 CC BOMBA RESERVOIR 12F DOUBLE***  
***PVC HEMOVAC DRAIN 250 CC BOMBA RESERVOIR 14F SINGLE***  
***PVC HEMOVAC DRAIN 250 CC BOMBA RESERVOIR 14F DOUBLE***  
***PVC HEMOVAC DRAIN 250 CC BOMBA RESERVOIR 16F SINGLE***  
***PVC HEMOVAC DRAIN 250 CC BOMBA RESERVOIR 16F DOUBLE***  
***PVC HEMOVAC DRAIN 250 CC BOMBA RESERVOIR 18F SINGLE***  
***PVC HEMOVAC DRAIN 250 CC BOMBA RESERVOIR 18F DOUBLE***

***PVC HEMOVAC DRAIN 400 CC BOMBA RESERVOIR 10F SINGLE***  
***PVC HEMOVAC DRAIN 400 CC BOMBA RESERVOIR 10F DOUBLE***  
***PVC HEMOVAC DRAIN 400 CC BOMBA RESERVOIR 12F SINGLE***  
***PVC HEMOVAC DRAIN 400 CC BOMBA RESERVOIR 12F DOUBLE***  
***PVC HEMOVAC DRAIN 400 CC BOMBA RESERVOIR 14F SINGLE***  
***PVC HEMOVAC DRAIN 400 CC BOMBA RESERVOIR 14F DOUBLE***  
***PVC HEMOVAC DRAIN 400 CC BOMBA RESERVOIR 16F SINGLE***  
***PVC HEMOVAC DRAIN 400 CC BOMBA RESERVOIR 16F DOUBLE***  
***PVC HEMOVAC DRAIN 400 CC BOMBA RESERVOIR 18F SINGLE***  
***PVC HEMOVAC DRAIN 400 CC BOMBA RESERVOIR 18F DOUBLE***

***PVC HEMOVAC DRAIN 600CC CC GUSSET RESERVOIR 10F SINGLE***  
***PVC HEMOVAC DRAIN 600CC CC GUSSET RESERVOIR 10F DOUBLE***  
***PVC HEMOVAC DRAIN 600CC CC GUSSET RESERVOIR 12F SINGLE***  
***PVC HEMOVAC DRAIN 600CC CC GUSSET RESERVOIR 12F DOUBLE***  
***PVC HEMOVAC DRAIN 600CC CC GUSSET RESERVOIR 14F SINGLE***  
***PVC HEMOVAC DRAIN 600CC CC GUSSET RESERVOIR 14F DOUBLE***

Doc. No.: 4A-FR-196

Publising date: 10.07.2015

Rev. Date / No.: 16.08.2021/ 07

*PVC HEMOVAC DRAIN 200 CC GUSSET RESERVOIR 16F SINGLE*  
*PVC HEMOVAC DRAIN 600CC CC GUSSET RESERVOIR 16F DOUBLE*  
*PVC HEMOVAC DRAIN 200 CC GUSSET RESERVOIR 18F SINGLE*  
*PVC HEMOVAC DRAIN 600CC CC GUSSET RESERVOIR 18F DOUBLE*

*PVC HEMOVAC DRAIN 800CC CC GUSSET RESERVOIR 10F SINGLE*  
*PVC HEMOVAC DRAIN 800CC CC GUSSET RESERVOIR 10F DOUBLE*  
*PVC HEMOVAC DRAIN 800CC CC GUSSET RESERVOIR 12F SINGLE*  
*PVC HEMOVAC DRAIN 800CC CC GUSSET RESERVOIR 12F DOUBLE*  
*PVC HEMOVAC DRAIN 800CC CC GUSSET RESERVOIR 14F SINGLE*  
*PVC HEMOVAC DRAIN 800CC CC GUSSET RESERVOIR 14F DOUBLE*  
*PVC HEMOVAC DRAIN 800CC CC GUSSET RESERVOIR 16F SINGLE*  
*PVC HEMOVAC DRAIN 800CC CC GUSSET RESERVOIR 16F DOUBLE*  
*PVC HEMOVAC DRAIN 800CC CC GUSSET RESERVOIR 18F SINGLE*  
*PVC HEMOVAC DRAIN 800CC CC GUSSET RESERVOIR 18F DOUBLE*

<b>REVISION HISTORY</b>		
<b>Rev. No:</b>	<b>Rev. Date:</b>	<b>Rev. Reason</b>
03	09.10.2019	<i>Revision history page has been added and the changes made are indicated in italics.</i>
04	03.02.2020	18F size added
05	04.05.2020	The review has been done.
06	01.10.2020	The review has been done.
07	16.08.2021	The review has been done.
08	12.01.2022	<i>Product codes have been added and standard dates have been reviewed.</i>