

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: Passive Chest Drainage Bottle (Single entrance)
Product Code: 4ACB2000
Product Models : *Chest Bottle (Single entrance) 2000ML*

Applicable directives: 93/42/EEC Medical Devices Directives, Attachment II Except Clause 4 (Class Is)
Classification: Class Is, rule 2, Attachment IX
GMDN No: 44643

Applicable Standards : TS EN ISO 14971:2019, TS EN ISO 24971:2020, EN ISO 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 10993-1:2020, 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

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. 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



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	17.06.2020	Standard dates have been revised.
05	16.08.2021	The review has been done.
06	12.01.2022	<i>Product codes have been added and standard dates have been updated.</i>