

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: Bomb Reservoir
Product Code: 4APVC-BR
Product Models: *PVC Bomb Reservoir 125CC*
PVC Bomb Reservoir 200CC
PVC Bomb Reservoir 250CC
PVC Bomb Reservoir 400CC

Applicable directives: 93/42/EEC Medical Devices Directives, Attachment II Except Clause 4 (*Class Is*)
conformity assessment according to rule 2.

Classification: *Class Is*, Attachment IX

GMDN No: 11301

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 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, TS EN 20697:2018

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. The product is safe under prescription and predictable storage and use conditions. We are conserving all corroborative documents in our own facility.

Place, Issue Date: *Ankara, 12.01.2022*

Canan ÖKTEM, General Manager

Signature & Stamp

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<i>REVISION HISTORY</i>		
<i>Rev. No:</i>	<i>Rev. Date:</i>	<i>Rev. Reason</i>
04	09.10.2019	<i>Revision history page has been added and the changes made are indicated in italics.</i>
05	01.10.2020	Review process has been done
06	09.11.2020	The class information of the product has been corrected.
07	16.08.2021	The review has been done.
08	12.01.2022	<i>Product codes have been added and standard dates have been updated.</i>