

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: Aspiration Handle (Yanquer Handle) (With vacuum / without vacuum)
Product Code: 4AYH
Product Models: *ASPIRATION HANDLE WITH VACUUM*
ASPIRATION HANDLE WITHOUT VACUUM

Applicable directives: 93/42/EEC Medical Devices Directives, Attachment II Except Clause 4 (Class IIa)
Classification: Class IIa, Rule 7, Attachment IX
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GMDN No: 35917

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 11737-2:2020, TS EN ISO 17141:2020, 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-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

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| <i>REVISION HISTORY</i> | | |
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| <i>Rev. No:</i> | <i>Rev. Date:</i> | <i>Rev. Reason</i> |
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| <i>01</i> | <i>16.08.2021</i> | <i>Standard dates and document validity period have been updated</i> |
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