

DECLARATION OF CONFORMITY

Manufacturer: DÖRT-A TIP MALZEMELERİ SAN. İTH. İHR. TİC. LTD. ŞTİ.
Address: Balıkhisar Mahallesi Köyiçi Serpmeleri No: 795/Akyurt / Ankara
Brand Name: Dört-A Medical
Product Name: Esu Pencil Cleaner
Product Code: 4AESUC
Applicable Directives: 93/42/EEC Medical Devices Directives, Except for Annex II Article 4 (Class Is)

Classification: Class Is, Rule 1, Attachment IX
GMDN No: 44681

Applicable Standards: EN 14971:2019, **EN ISO 15223-1:2021**, ISO 9001:2015, ISO 13485:2016, EN 60601-1-1:2009, EN 60601-2-2:2018, **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 17141-1:2020, TS EN 62366-1:2015, TS EN 60601-1-2:2016, 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 ISO 10993-18:2020

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

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**Dört-A Tıp Malzemeleri
Sanayi İth. İhr. Tic. Ltd. Şti.**

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<i>REVISION HISTORY</i>		
<i>Rev. No:</i>	<i>Rev. Date:</i>	<i>Rev. Reason</i>
<i>06</i>	<i>12.01.2021</i>	<i>Product codes have been added and revision history page has been added and the changes made are indicated in italics. The standards have been updated.</i>

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