

DECLARATION OF CONFORMITY

Manufacturer: DÖRT-A TIP MALZEMELERİ SAN. İTH. İHR. TİC. LTD. ŞTİ.
Address: Balıkhisar Mahallesi Köyüçü Serpmeleri No: 795/A Akyurt / Ankara
Brand Name: Dört-A Medical
Product Name: Esu Pencil
Product Code: 4AESU

Product Models: *TRIPLE ENTRY HAND CONTROL ESU PENCIL*

Applicable directives: 93/42/EEC Medical Devices Directives, Attachment II Except Clause 4 (Class IIb)

Classification: Class IIb, Rule 9, Attachment IX

GMDN No: 44681

Applicable Standards:

TS EN 14971:2019, EN 24971:2020, **EN ISO 15223:2021**, ISO 9001:2015, ISO 13485:2016, IEC 60601-1:2009, TS EN IEC 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 10993-12:2013**, TS EN ISO 11135:2014, TS EN ISO 14937:2011, TS EN ISO 11607-1:2020, TS EN ISO 11607-2:2020, TS EN ISO 17141:2020, TS EN 62366-1:2015, TS EN 60601-1-2:2016, TS EN ISO 10993-1:2021, 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. Ltd. Şti*

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

Doc. No.: 4A-FR-208
Publishing Date: 11.07.2016
Rev. Date / No.: 02.08.2021/10



REVISION HISTORY		
Rev. No:	Rev. Date:	Rev. Reason
06	08.10.2019	<i>Revision history page has been added and the changes made are indicated in italics.</i>
07	19.08.2020	Standards have been reviewed.
08	16.10.2020	TS EN 60601-2-2: 2013 standard is removed because it was canceled.
09	19.01.2021	Standard checks have been done The TS EN 14698 standard has been removed because it was canceled.
10	02.08.2021	TS EN 1041+2014 (replaced standard; TS EN 20417:2021) standard has been removed because it is cancelled. The 10993 standard has been updated. Document validity date has been changed.
11	12.01.2022	<i>Product codes have been added and standards have been reviewed.</i>