

## DECLARATION OF CONFORMITY

**Manufacturer:** DÖRT-A TIP MALZEMELERİ SAN. İTH. İHR. TİC. LTD. ŞTİ.  
**Address:** Balıkhisar Mahallesi Köyü Serpmeleri No: 795/Akyurt / Ankara  
**Brand Name:** Dört-A Medical  
**Product Name:** Esu Pencil Blade  
**Product Code:** 4AESUT  
**Applicable Directives:** 93/42/EEC Medical Devices Directives, Attachment II Except Clause 4 (Class IIb)

**Classification:** Class Is, Rule 1, Attachment IX

**GMDN No:** 44681

**Applicable Standards:** EN 14971:2020, EN ISO 15223:2021, ISO 9001:2015, ISO 13485:2016, EN 60601-1-1:2015, EN 60601-2-2:2014, TS EN ISO 20417, 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 17141:2020, 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

Doc. No.: 4A-FR-207  
First Publishing Date: 11.07.2016  
Rev. Date / No.: 12.01.2021/ 04

**4a medical** Dört-A Tıp Malzemeleri  
producing health for the world Sanayi İth. İhr. Tic. Ltd. Şti.  
Balıkhisar Mahallesi Köyü Serpmeleri No: 795/A  
Tel: 0312 363 50 52-53 Fax: 363 52 10 Akyurt-ANKARA  
Çubuk Vergi Dairesi: 313 006 8100 Ankara-Birlik No: 795  
http://www.4amedical.com • ankara@4amedical.com  
Mersis No: 0313 006 8100 0018

<b><i>REVISION HISTORY</i></b>		
<b><i>Rev. No:</i></b>	<b><i>Rev. Date:</i></b>	<b><i>Rev. Reason</i></b>
<b><i>04</i></b>	<b><i>12.01.2022</i></b>	<b><i>Product codes have been added and standard checks have been done and dates have been added. Revision history has been added.</i></b>