

**Annex of the certificate (Page 1/1)**  
**Accreditation Scope**

 <p>Kalite Yönetim Sistemi TS EN ISO/IEC 17021-1 AB-0049-YS</p>	<b>UDEM ULUSLARARASI BELGELENDİRME DENETİM EĞİTİM MERKEZİ SANAYİ ve TİC. A.Ş.</b> Accreditation Nr: AB-0049-YS Revision Nr: 015 Date: 02 October 2018	
	<b>TS EN ISO 9001: 2015 Quality Management System Certification</b>	
<b>Address :</b> Mutlukent Mahallesi 2073 Sokak No:10 Ümitköy 06810 ANKARA/TÜRKİYE	<b>Phone :</b> 0312 443 03 90 <b>Fax :</b> 0312 443 03 76 <b>E-Mail :</b> info@udemltd.com.tr <b>Website :</b> http://www.udem.com.tr/	

* EA Code	Description
01	Agriculture, forestry and fishing
03	Food products, beverages and tobacco
04	Textiles and textile products
12	Chemicals, chemical products and fibres
14	Rubber and plastic products
15	Non-metallic mineral products
16	Concrete, cement, lime, plaster etc.
17	Basic metals and fabricated metal products
18	Machinery and equipment
19	Electrical and optical equipment
22	Other transport equipment
23	Manufacturing not elsewhere classified
28	Construction
29	Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods
30	Hotels and restaurants
31	Transport, storage and communication
32	Financial intermediation; real estate; renting
33	Information technology
34	Engineering services
36	Public administration
37	Education
39	Other social services

END of SCOPE

**Kadir Kayıhan CABIOĞLU**  
Deputy Secretary General

\* The accreditation is granted for the NACE codes included by EA scopes given above. The certification body shall not issue certificates for the NACE codes which it does not have enough competency (Personel,resources, etc). (See TÜRKAK R40.01/02)

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 <p>Tibbi Cihazlar K. Y. S. TS EN ISO/IEC 17021-1 AB-0049-YS</p>	<b>UDEM ULUSLARARASI BELGELENDİRME DENETİM EĞİTİM MERKEZİ SANAYİ ve TİC. A.Ş.</b> Accreditation Nr: AB-0049-YS Revision Nr: 015 Date: 02 October 2018	
	ISO 13485: 2003/TS EN ISO 13485: 2012 (31.03.2019 tarihine kadar geçerlidir) TS EN ISO 13485: 2016 Medikal Cihazlar Y.S. Belgelendirmesi	
<b>Address :</b> Mutlukent Mahallesi 2073 Sokak No:10 Ümitköy 06810 ANKARA/TÜRKİYE		<b>Phone</b> :0312 443 03 90 <b>Fax</b> : 0312 443 03 76 <b>E-Mail</b> :info@udemltd.com.tr <b>Website</b> :http://www.udem.com.tr/

* EA Code	Description
Non-active Medical Devices	General non-active, nonimplantable medical devices Non-active implants Devices for wound care Non-active dental devices and accessories Non-active medical devices other than specified above
Active Medical Devices (NonImplantable)	General active medical devices Devices for imaging Monitoring devices Devices for radiation therapy and thermo therapy Active (non-implantable) medical devices other than specified above
Sterilization Method for Medical Devices	Ethylene oxide gas sterilization (EOG) Moist heat Aseptic processing Radiation sterilization (e.g. gamma, x-ray, electron beam) Sterilization method other than specified above
Devices incorporating / utilizing specific substances/ technologies	Medical devices incorporating medicinal substances Medical devices utilizing tissues of animal origin Medical devices incorporating derivatives of human blood Medical devices utilizing micromechanics Medical devices utilizing nanomaterials Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed Medical devices incorporating or utilizing specific substances/technologies/elements, other than specified above

END of SCOPE

**Kadir Kayıhan CABIOĞLU**  
Deputy Secretary General