


Attachment of Accreditation Certificate

SCOPE OF ACCREDITATION

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 TESTING LABORATORY ISO/IEC 17025:2017 NAC-003-TL	NAC ACCREDITATION NUMBER	NAC-003-TL
	COMPANY NAME	TECHNICAL UNIVERSAL VERIFICATION BELGELENDİRME VE EĞİTİM HİZMETLERİ LİMİTED ŞİRKETİ
	ADDRESS	MACUN MAH. BATI BULVARI ATB İŞ MERKEZİ NO:1/3 YENİMAHALLE - ANKARA / TURKEY
	CONTACT NAME	Serdar AYYILDIZ
	TELEPHONE	0 312 231 82 02
	ACCREDITATION DATE	5.12.2020
	ACCREDITATION STANDARD	ISO/IEC 17025:2017

Accreditation Area	General requirements for the competence of testing and calibration laboratories	
Accreditation Standard	ISO/IEC 17025:2017	
Certification Sectors		
Test material/ Products	Test Name	Test Method (National-International standards in-House methods)
Medical Device	Irritation, Sensization, Cytotoxicity, Implantation, Subchronic Toxicity, Subacute Toxicity, Genotoxicity, Pyrogenity, Hemocompatibility Acut Sistematic Toxicity, Acute Dermal Irritation Biocompatibility Test	ISO 10993 OECD 471 OECD 487 OECD 404
Orthopedic Implant	Biomechanical Testing	ASTM F 1829,ASTM F2028, ASTM F1264,ASTM F1541, ASTM F 2346,ASTM F2193, ISO 6892-1,ASTM F2887, ASTM F2665,ASTM F1717, ASTM F1798,ASTM F 2077, ASTM F 2267,ASTM F 382, ASTM F 384,ASTM F 543 ISO 18192, ASTM F2423 , ASTM F1781, ISO 14801 , ISO/TS 13498, ASTM F1378, ASTM F1357,ASTM F2502




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Certification Sectors		
Test material/ Products	Test Name	Test Method (National-International standards in-House methods)
Knee Prostheses	Biomechanical Testing	ISO 14243, ISO 14879 ASTM F1800, ASTM F 2777 ASTM F 2722, ASTM F 2724 ASTM F1223, ISO 7207ASTM F2083 , ISO 21536, ASTM F1672, ASTM F2791 , ASTM F2723, ASTM F3141, ASTM F3161, ASTM F1814, ISO 21534
Hip Prostheses	Biomechanical Testing	ISO 14242 ISO 7206 ASTM F1820, ASTM F2009, ASTM F2580, ASTM F3047M, ISO 11491, ASTM F2996, ASTM F2068, ASTM F1875, ASTM F2582 ISO 21534 ISO 21535



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Certification Sectors		
Test material/ Products	Test Name	Test Method (National-International standards in-House methods)
Biological And Security Tests For Medical Devices	-Sterility Test	ISO 11737-2 European Pharmacopoeia
	Determination of Microorganism Population on Medical Material (bioburden)	ISO 11737-1 European Pharmacopoeia
	Impermeability	ASTM F 1929
	Standard Test Method for Adhesion Strength of Flexible Barrier Materials	ASTM F88/F88M - Metot A TS EN 868-5
	Bacterial Endotoxin (LAL) Test Gel Clot Method	USP NF (85) USP NF (161)
	Determination of Oil-Grease Residue	SM 5520-B ASTM F2459-18 ASTM F2459
	Detergent Residue Determination	ISO 2271 ASTM F2459-18
	Ethylene Oxide (C ₂ H ₄ O) Residue Determination GC - Headspace Method	10993-7
	Ethylene Chlorine Hydrin (HOCH ₂ CH ₂ Cl) Residue Determination GC - Headspace Method	10993-7




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Certification Sectors		
Test material/ Products	Test Name	Test Method (National-International standards in-House methods)
Biological And Security Tests For Medical Devices (Continue)	Surgical Implants - Cleaning Orthopedic Implants	ISO 19227
	Accelerated Shelf Life	ASTM F1980
	Aerobic mesophilic bacteria * Mold-Yeast *	ISO 14698-1 ISO 14698-2
	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)	ASTM F2096
Synthetic grafts	In Vivo Evaluation of Osteoinductive Potential for Materials Containing Demineralized Bone	ASTM F2529 – 13 ISO 5833
	Standard Specification for Beta- Tricalcium Phosphate for Surgical Implantation	ASTM F1088 - 04a ISO 13175-3
Biomechanical tests for Dental Materials	Dentistry — Bonding test between polymer teeth and denture base	ISO 19736
	Ceramic materials	ISO 6872:2015
	Polymer based restorative materials	ISO 4049:2019



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Accreditation Standard	ISO/IEC 17025:2017	
Certification Sectors		
Test material/ Products	Test Name	Test Method (National-International standards in-House methods)
Catheters, Infusion Equipment and Accessories	Mechanical and General Properties, Performance requirements	EN 20594, ISO 20695, ISO 20696, ISO 20697, ISO 20698, ASTM F1828-97, ISO 11070, ISO 10555-1, ISO 10555-2, ISO 10555-3, ISO 10555-4, ISO 10555-5, ISO 10555-6, ASTM F640-12, ISO 7886-1, ISO 594-2, ISO 594-1, ISO 7864, EN 1618, EN 1707, ISO 80369, ISO 5361, ISO 8536
Wound Closure Materials	Performance Tests	ISO 13726-1, ISO 13726-2, ISO 13726-3, ISO 13726-4, ISO 13726-5, ISO 13726-6
Aseptic Processing of Health Products	Performance Requirements	EN ISO 13408-1, EN ISO 13408-2, EN ISO 13408-3, EN ISO 13408-4, EN ISO 13408-5, EN ISO 13408-6, EN ISO 13408-7
Chemical Disinfectants	Performance Requirements	EN 15024, EN 15727, EN 14561, EN 14562, EN 14563
Hemodialysis	Performance Requirements	ISO 8637-2



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Biocompatibility	Bakterial Endotoxins	PHARMACOPEİAE (E.P) 2.6.14
	Bakterial Endotoxins Test	UNITED STATES PHARMACOPEİAE (USP) 85
Biomechanics	Dentistry – Screw Loosening Test	ISO 18130
Microbiology	Chemical Disinfectants and Antiseptics - Virus Killing Suspension	TS EN 14476
	Chemical Disinfectants and Antiseptics - Nice Suspension Test	TS EN 13727
	Chemical Disinfectants and Antiseptics - Fungicidal efficacy test	TS EN 13624



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