



TURKISH ACCREDITATION AGENCY

ACCREDITATION CERTIFICATE

As a Testing Laboratory

KOBAY DENEY HAYVANLARI LABORATUVARI SANAYİ VE TİCARET A.Ş.

Central Address: OSTİM MAH. 1308 CAD. ODTÜ TEKNOKENT OSTİM NO:6/1 YENİMAHALLE Ankara / Türkiye

is accredited in accordance with TS EN ISO/IEC 17025:2017 standard within the scope given in Annex following the assessment conducted by TURKAK.

Accreditation Number : AB-1699-T

Accreditation Date : 23.09.2021

Revision Date / Number : 12.05.2023 / 02


This certificate shall remain in force until **22.09.2025**, subject to continuing compliance with the standard **TS EN ISO/IEC 17025:2017**, related regulations and requirements.

Gülden Banu Müderrisoğlu
Secretary General




Turkish Accreditation Agency (TURKAK) is a signatory to the European co-operation for Accreditation (EA) Multilateral Agreement (MLA) and International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA) in the scope of ISO/IEC 17025.

This document has been signed by Gülden Banu Müderrisoğlu on {1} with a secure electronic signature in accordance with the electronic signature law numbered 5070. Use the QR code to verify the e-signed document.

 <p>Test TS EN ISO/IEC 17025 AB-1699-T</p>	KOBAY DENEY HAYVANLARI LABORATUVARI SANAYİ VE TİCARET A.Ş.	
	Accreditation Nr: AB-1699-T Revision Nr: 02 Date: 12.05.2023	
Testing Laboratory		
Address : OSTİM MAH. 1308 CAD. ODTÜ TEKNOKENT OSTİM NO:6/1 YENİMAHALLE Ankara / Türkiye	Phone : +90 312 394 7094 Fax : - Email : bilgi@kobay.com.tr Website : www.kobay.com.tr	

Medical Devices		
Tested Materials / Products	Name of Test	Testing Method (National, International Standards, In-house Methods)
Medical Device Finished Product Medical Equipment Medical Products	In vitro Cytotoxicity Test	TS EN ISO 10993-5 ISO 10993-5 TS EN ISO 10993-12 ISO 10993-12
Medical Device Finished Product Medical Equipment Medical Products	Sensitization Test Guinea Pig Maximization Test	TS EN ISO 10993-2 ISO 10993-2 TS EN ISO 10993-12 ISO 10993-12 TS EN ISO 10993-10 ISO 10993-10
Medical Device Finished Product Medical Equipment Medical Products	Irritation Test -Intracutaneous (intra dermal) Reactivity Test -Dermal Irritation Test -Ocular Irritation Test -Vaginal Irritation Test -Rectal Irritation Test -Penile Irritation Test -Oral Irritation Test	TS EN ISO 10993-2 ISO 10993-2 TS EN ISO 10993-23 ISO 10993-23 TS EN ISO 10993-12 ISO 10993-12
Medical Device Finished Product Medical Equipment Medical Products	Acute Dermal Irritation Test	OECD TG 404
Medical Device Finished Product Medical Equipment Medical Products	Systemic Toxicity Test -Acute Systemic Toxicity -Repeated Dose Systemic Toxicity	TS EN ISO 10993-2 ISO 10993-2 TS EN ISO 10993-11 ISO 10993-11 TS EN ISO 10993-12 ISO 10993-12
Medical Device Finished Product Medical Equipment Medical Products	Local Effects After Implantation -Implantation -Evaluation	TS EN ISO 10993-2 ISO 10993-2 TS EN ISO 10993-6 ISO 10993-6
Medical Device Finished Product Medical Equipment Medical Products	Genotoxicity Test	TS EN ISO 10993-3 ISO 10993-3 OECD TG 487
Medical Device Finished Product Medical Equipment Medical Products	Interaction with Blood Test	TS EN ISO 10993-4 ISO 10993-4
Medical Device Finished Product Medical Equipment Medical Products	Invivo Pyrogenicity Test	European Pharmacopoeia 10.0 (2.6.8)
Medical Device Finished Product Medical Equipment Medical Products	Invivo Abnormal Toxicity Test	European Pharmacopoeia 9.0 (2.6.9)
Medical Device Finished Product Medical Equipment Medical Products	Bacterial Reverse Mutation Test	OECD TG 471 TS EN ISO 10993-12 ISO 10993-12



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Veterinary Testing

Tested Materials / Products	Name of Test/Examination Method/Parameter/Analyte	Testing Method (National, International Standards, In-house Methods)
Experimental Animal Samples (Feather, Saliva, Stool)	Taking samples for parasitological, bacteriological, virological testing	"In-house Method- "KBY_ILU_PR_39/Rev02" (Modified from FELASA guidelines.)
Experimental Animal Samples (Feather, Saliva, Stool)	Detection and Identification of Some Parasites (<i>Syphacia</i> spp., <i>Passalurus</i> spp., <i>Eimeria</i> spp., <i>Giardia</i> spp., <i>Aspiculuris</i> spp.) Flotation Method and Microscopic Method	"In-house Method- "KBY_ILU_PR_39/Rev02" (Modified from FELASA guidelines.)
Experimental Animal Samples (Feather, Saliva, Stool)	Detection and Identification of Some Viruses (<i>Mouse adenovirus</i> , <i>Minute virus</i> , <i>Mouse parvovirus</i>) and Bacteria (<i>Citrobacter rodentium</i> , <i>Helicobacter pylori</i> , <i>Streptococcus pneumonia</i> , <i>Corynebacterium kutscheri</i> , <i>Rodentibacter pneumotropicus</i> , <i>Streptobacillus moniliformis</i> ve <i>Streptococcus agalactiae</i>) Real Time PCR	"In-house Method- "KBY_ILU_PR_39/Rev02" (Modified from FELASA guidelines.)

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