



TURKISH ACCREDITATION AGENCY

## ACCREDITATION CERTIFICATE

As a Testing Laboratory

**KOBAY DENEY HAYVANLARI LABORATUARI SANAYİ VE TİCARET A.Ş.**

Central Address: OSTİM MAH. 1308 CAD. NO:6 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 : 06.10.2021 / 01**

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 08.10.2021 with a secure electronic signature in accordance with the electronic signature law numbered 5070. Use the QR code to verify the e-signed document.*

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|------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|
|  <p>Test<br/>TS EN ISO/IEC 17025<br/>AB-1699-T</p> | <p><b>KOBAY DENEY HAYVANLARI LABORATUARI SANAYİ VE TİCARET A.Ş.</b><br/>Accreditation Nr: AB-1699-T<br/>Revision Nr: 01 Date: 06.10.2021</p> |                                                                                                 |
|                                                                                                                                    | Testing Laboratory                                                                                                                           |                                                                                                 |
|                                                                                                                                    | Address :<br>OSTİM MAH. 1308 CAD. NO:6 YENİMAHALLE Ankara / Türkiye                                                                          | Phone : +90 312 394 7094<br>Fax : -<br>Email : bilgi@kobay.com.tr<br>Website : www.kobay.com.tr |

## Medical Devices

| Tested Materials / Products        | Name of Test                                                                                                                                                                                                                      | Testing Method (National, International Standards, In-house Methods) |
|------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|
| Polymeric and Elastomeric Plastics | In vitro Cytotoxicity Test                                                                                                                                                                                                        | TS EN ISO 10993-5<br>TS EN ISO 10993-12                              |
| Polymeric and Elastomeric Plastics | Sensitization Test<br>Guinea Pig Maximization Test                                                                                                                                                                                | TS EN ISO 10993-2<br>TS EN ISO 10993-10<br>TS EN ISO 10993-12        |
| Polymeric and Elastomeric Plastics | Irritation Test<br>-Intracutaneous (intradermal) Reactivity Test<br>-Dermal Irritation Test<br>-Ocular Irritation Test<br>-Vaginal Irritation Test<br>-Rectal Irritation Test<br>-Penile Irritation Test<br>-Oral Irritation Test | TS EN ISO 10993-2<br>TS EN ISO 10993-10<br>TS EN ISO 10993-12        |
| Polymeric and Elastomeric Plastics | Acute Dermal Irritation Test                                                                                                                                                                                                      | OECD TG 404                                                          |
| Polymeric and Elastomeric Plastics | Systemic Toxicity Test<br>-Acute Systemic Toxicity<br>-Repeated Dose Systemic Toxicity                                                                                                                                            | TS EN ISO 10993-2<br>TS EN ISO 10993-11<br>TS EN ISO 10993-12        |
| Polymeric and Elastomeric Plastics | Local Effects After Implantation<br>-Implantation<br>-Evaluation                                                                                                                                                                  | TS EN ISO 10993-2<br>TS EN ISO 10993-6                               |
| Polymeric and Elastomeric Plastics | Genotoxicity Test                                                                                                                                                                                                                 | TS EN ISO 10993-3<br>OECD TG 487                                     |
| Polymeric and Elastomeric Plastics | Interaction with Blood Test                                                                                                                                                                                                       | TS EN ISO 10993-4                                                    |



## Accreditation Scope

|                                                                                                                              |                                                                                                                                     |                                     |
|------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| <br>Test<br>TS EN ISO/IEC 17025<br>AB-1699-T | <b>KOBAY DENEY HAYVANLARI LABORATUARI SANAYİ VE TİCARET A.Ş.</b><br>Accreditation Nr: AB-1699-T<br>Revision Nr: 01 Date: 06.10.2021 |                                     |
|                                                                                                                              | Testing Laboratory<br><br>Address :<br>OSTİM MAH. 1308 CAD. NO:6 YENİMAHALLE Ankara / Türkiye                                       |                                     |
| Phone : +90 312 394 7094<br>Fax : -<br>Email : bilgi@kobay.com.tr<br>Website : www.kobay.com.tr                              |                                                                                                                                     |                                     |
| Polymeric and Elastomeric Plastics                                                                                           | Invivo Pyrogenicity Test                                                                                                            | European Pharmacopoeia 10.0 (2.6.8) |
| Polymeric and Elastomeric Plastics                                                                                           | Invivo Abnormal Toxicity Test                                                                                                       | European Pharmacopoeia 10.0 (2.6.9) |

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