



REPUBLIC OF TURKEY
MINISTRY OF HEALTH
Turkish Medicines and Medical Devices Agency

Privacy Statement Regarding

European Database on Medical Devices (EUDAMED)

This clarification text has been prepared as per Article 10 of The Personal Data Protection Law No. 6698 (KVKK, the Law).

Identity of Data Controller

In terms of personal data processing activities carried out in Turkey regarding the European Database for Medical Devices (EUDAMED) system, the data controller is the Turkish Medicines and Medical Devices Agency (TİTCK).

Purpose of Processing of Personal Data

Within the scope of our obligations related to the EUDAMED system pursuant to the Regulation on Medical Device (Regulation (EU) 2017/745) and the Regulation on In Vitro Diagnostic Medical Device ((EU) 2017/746 Regulation) your personal data is processed.

Which personal data is processed in the EUDAMED system?

EUDAMED primarily includes data belonging to the natural persons representing economic operators (i.e. manufacturers, authorised representatives, importers, systems and procedure pack producers), person(s) responsible for regulatory compliance, notified bodies, sponsors, researchers, legal representatives, expert panels, ethics committee members, the National Competent Authorities and the European Commission staff.

The personal data of data subjects in the EUDAMED system are related to their identity and contact details, and data on name, surname, phone number, street, city, zip code, country, e-mail address and website, as well as data on professional qualifications in the case of person(s) performing clinical investigation are processed by TİTCK.

Transfer of Personal Data

Data transferred from the EUDAMED system to TİTCK will not be transferred to third parties.

Personal Data Collection Procedure and Its Legal Justification

Personal data are obtained automatically through the EUDAMED system and the collection of personal data takes place on the basis of the condition that "obligatory for the data controller to fulfill his legal obligation" regulated in the article 5(2)(ç) titled "Conditions for processing personal data" of the Law within the framework of the article 30 and article 33(2)(c) of the Regulation on Medical Device¹, and the article 27 and article 30(2)(c) of the Regulation on In Vitro Diagnosis Medical Diagnostic Medical Devices².

How do we protect and retain your information?

Processing of information transferred from the EUDAMED system to TİTCK is carried out, only with a personalized user name and password, by personnel authorized by TİTCK in this regard and via limited electronic means within the scope of its duty in TITCK.

What are your rights?

As a data subject, you have the following rights pursuant to Article 11 of the Law No. 6698:

- Learn whether or not your personal data are being processed,

¹ Regulation on Medical Device published in the Official Gazette dated 02.06.2021 and numbered 31499 (repeated)

² Regulation on In Vitro Diagnosis Medical Diagnostic Medical Devices published in the Official Gazette dated 02.06.2021 and numbered 31499 (repeated)



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- Request further information about processing if your personal data are being processed,
- Learn the purpose of processing of your personal data and whether personal data are being used consistently with that purpose,
- Know the third parties in the country or abroad to whom your personal data are transferred,
- Request rectification of your personal data in case of incomplete or incorrect processing and request reporting of the operations carried out within that scope to the third parties to whom the personal data have been transferred,
- Request erasure or destruction of personal data in the event that the reasons necessary for being processed disappear, although it has been processed in accordance with the provisions of the Law No. 6698 and other relevant laws, and request reporting of the operations carried out within that scope to the third parties to whom the personal data have been transferred,
- Object to the processing, exclusively by automatic means of your personal data, which leads to an unfavourable consequence for the data subject,
Request compensation for the damage arising from the unlawful processing of your personal data.

However, in cases where the application made to the data controller is refused, the response is found insufficient or the response is not given within the specified time period; you have the right to complain to the Personal Data Protection Board in our country within thirty days as of you learn about the response of the data controller, or within sixty days as of the application date, in any case. It is not obligatory to be a citizen of the Republic of Turkey in order to lodge a complaint with the Board within the scope of the implementation of the Law.

In this context, it is possible either to apply to the jurisdiction directly or also to make a complaint with the Board. At this point, filing a complaint with the Board is not a prerequisite for applying to the jurisdiction.

On the other hand, natural and legal persons who are not citizens of the Republic of Turkey have the right to file a lawsuit in Turkish courts pursuant to the third paragraph of Article 35 titled “Liability for Violation of Personally Rights” and Article 48 titled “Security Payment” of the Turkish Act on Private International Law and International Civil Procedure numbered 5718.

You can use your rights by contacting TİTCK. You can find the contact information below.

How long do we keep your data?

Personal data of individuals belonging to Economic Operators, to TİTCK and to Competent Authorities of EU in the field of medical device, and of Commission staff are deleted from the database as soon as the individual is no longer designated as contact person.

TİTCK will not retain personal data for longer than is necessary and appropriate for the purpose for which the data are processed.

Contact Information

If you have questions concerning the processing of your personal data transferred from the EUDAMED system to TİTCK or your rights with respect to that processing, you may contact at the following address:

Harmonization of EU Legislation Unit
Department of Notified Body and Clinical Investigations for Medical Devices
Vice Presidency of Medical Devices and Cosmetics
Turkish Medicines and Medical Devices Agency (TİTCK)

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