

# PRIVACY STATEMENT

## European Database for Medical Devices EUDAMED

### 1. The EUDAMED portal, purpose of processing, competent controller and applicable law

The European Databank for Medical Devices (EUDAMED) is a secure web-based portal that supports the implementation of [Regulation \(EU\) 2017/745](#) of the European Parliament and of the Council of 5 April 2017 on medical devices and [Regulation \(EU\) 2017/746](#) of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.

EUDAMED is to be used by Economic Operators (i.e. manufacturers, authorised representatives, systems and procedure pack producers, importers) and by the National Competent Authorities.

Information contained in EUDAMED includes personal data, such as the contact details of individuals belonging to the Economic Operators, to the National Competent Authorities and of the Commission staff.

This information is entered by the Economic Operators themselves, by the National Competent Authorities and by the Directorate General on Health and Food Safety (DG SANTE) services. The processing of this personal data is under the responsibility of the European Commission, Directorate General for Health and Food Safety, Unit SANTE.B6 "Medical Devices and HTA" acting as the Controller.

The personal data of individuals belonging to the Economic Operators may be downloaded afterwards into the national databases of the National Competent Authorities.

The related processing of personal data is subject to Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data.

### 2. What personal data are processed within EUDAMED?

The processing of personal data within EUDAMED is based on [Regulation \(EU\) 2017/745](#) on medical devices (Article 30 and Article 33(2)(c)) and [Regulation \(EU\) 2017/746](#) on in vitro diagnostic medical devices (Article 27 and Article 30(2)(c)).

The following personal data relating to contact details of individuals belonging to Economic Operators, to National Competent Authorities and of Commission staff are processed in EUDAMED (mandatory data fields are marked with an asterisk):

- First Name (\*)

- Last Name (\*)
- Phone number (\*)
- Street (\*)
- City name (\*)
- Postal code (\*)
- Country (\*)
- Email (\*)
- Website

### **3. Who has access to your information and to whom is it disclosed?**

The information entered in EUDAMED is disclosed to the European Commission's staff, to the National Competent Authorities and to the public.

### **4. How do we protect and safeguard your information?**

The collected personal data are stored in servers of the Data Centre of the European Commission's Directorate-General for Informatics, the operations of which underlie the Commission's security decisions and provisions established by the Security Directorate for this kind of servers and services.

Access to personal data is only granted through personalised user ID and Password.

### **5. What are your rights?**

You have specific rights as a 'data subject' under Chapter III (Articles 14-25) of Regulation (EU) 2018/1725, in particular the right to access your personal data and to rectify them in case your personal data is inaccurate or incomplete. Under certain conditions, you have the right to erase your personal data, to restrict the processing of your personal data, to object to the processing and the right to data portability.

You have the right to object to the processing of your personal data, which is lawfully carried out pursuant to Article 5(1)(a), on grounds relating to your particular situation.

You can exercise your rights by contacting the Data Controller, or in case of conflict the Data Protection Officer. If necessary, you can also address the European Data Protection Supervisor. You can find their contact information below.

### **6. How long do we keep your data?**

Personal data of individuals belonging to Economic Operators, to National Competent Authorities and of Commission staff are deleted from the database as soon as the individual is no longer designated as a contact person.

## **7. Contact information**

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

Unit SANTE.B6 – Medical Devices  
Directorate-General on Health and Food Safety (DG SANTE)  
European Commission  
200 rue de la Loi  
B - 1049 Brussels  
Belgium  
[SANTE-MED-DEV@ec.europa.eu](mailto:SANTE-MED-DEV@ec.europa.eu)

or the Data Protection Officer of the European Commission at:

[DATA-PROTECTION-OFFICER@ec.europa.eu](mailto:DATA-PROTECTION-OFFICER@ec.europa.eu).

## **8. Recourse**

Complaints against any data processing act executed under the Commission's responsibility can be addressed to the European Data Protection Supervisor at the following address:

European Data Protection Supervisor (EDPS)  
Rue Wiertz 60  
B-1047 Brussels  
Belgium  
Phone: +32 2 283 19 00  
Fax: +32 2 283 19 50  
[edps@edps.europa.eu](mailto:edps@edps.europa.eu)