



EUROPEAN COMMISSION

PROTECTION OF YOUR PERSONAL DATA

This privacy statement provides information about the processing and the protection of your personal data.

Processing operation: European Database on Medical Devices - MDR Eudamed

Data Controller: Directorate General for Health and Food Safety – DG Sante, Directorate D - Medical products and innovation, Unit D3 – Medical Devices

Record reference: DPR-EC-06787

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1. Introduction

The European Commission (hereafter ‘the Commission’) is committed to protect your personal data and to respect your privacy. The Commission collects and further processes personal data pursuant 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 (repealing Regulation (EC) No 45/2001).

This privacy statement explains the reason for the processing of your personal data, the way we collect, handle and ensure protection of all personal data provided, how that information is used and what rights you have in relation to your personal data. It also specifies the contact details of the responsible Data Controller with whom you may exercise your rights, the Data Protection Officer and the European Data Protection Supervisor.

The information in relation to processing operation “MDR Eudamed” (Medical Devices Regulations, European Database on Medical Devices) undertaken by Directorate-General for Health and Food Safety (DG SANTE), Directorate D – Medical products and innovation, Unit SANTE.D3 – Medical Devices, is presented below.

2. Why and how do we process your personal data?

Purpose of the processing operation: Directorate-General on Health and Food Safety (DG SANTE), Directorate D – Medical products and innovation, Unit SANTE.D3 – Medical Devices collects and uses your personal information to comply with: Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR) ¹.

The purposes of the MDR Eudamed are:

- to enable the public to be adequately informed about devices placed on the market, the corresponding certificates issued by notified bodies and about the relevant economic operators;
- to enable unique identification of devices within the internal market and to facilitate their traceability;
- to enable the public to be adequately informed about clinical investigations and to enable sponsors of clinical investigations to comply with obligations under Articles 62 to 80, Article 82, and any acts adopted pursuant to Article 81;
- to enable manufacturers to comply with the information obligations laid down in Articles 87 to 90 or in any acts adopted pursuant to Article 91;
- to enable the competent authorities of the Member States and the Commission to carry out their tasks relating to this Regulation on a well-informed basis and to enhance the cooperation between them

Consequently, the personal data processed for the purposes above is linked to the identification of the users and contact points of Commission staff, national competent authorities, notified bodies, sponsors, economic operators, investigators, the persons responsible for regulatory compliance and the experts qualified in the assessment of conformity assessment bodies is needed.

Your personal data will not be used for an automated decision-making including profiling.

¹ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

3. On what legal ground(s) do we process your personal data

Processing operation is compliant with each of the principles listed below.

Article 5(1) of Regulation (EU) 2018/1725²:

- 5(1)(a) Processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the Union institution or body
- 5(1)(b) Processing is necessary for compliance with a legal obligation to which the controller is subject

Legal basis: Regulations (EU) 2017/745 and (EU) 2017/746.

4. Which personal data do we collect and further process?

Data subjects:

- Commission staff as MDR EUDAMED users;
- The individuals designated by the national competent authorities as contacts and as MDR EUDAMED users;
- The individuals designated by economic operators, notified bodies, sponsors, investigators and the persons responsible for regulatory compliance and as MDR EUDAMED users;
- experts qualified in the assessment of conformity assessment bodies nominated by the member states (according to Article 40 MDR).

In order to carry out this processing operation Directorate-General on Health and Food Safety (DG SANTE), Directorate D – Medical products and innovation, Unit SANTE.D3 – Medical Devices collects the following categories of personal data.

The following personal data relating to contact details of individuals belonging to Economic Operators, National Competent Authorities, notified bodies, investigators, sponsors, persons responsible for regulatory compliance 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

In addition, for the list, maintained by the Commission, of experts qualified in the assessment of conformity assessment bodies nominated by the member states (according to Article 40 MDR and 36 IVDR), the following data are processed:

- First Name (*)
- Last Name (*)
- Information on specific field of competence and expertise

In cases where the data is not collected directly from the data subject, the data has been obtained from *other Units in DG SANTE, and from authorised users of Eudamed* (national competent authorities, notified bodies, sponsors, economic operators).

5. How long do we keep your personal data?

Directorate-General on Health and Food Safety (DG SANTE), Directorate D – Medical products and innovation, Unit SANTE.D3 – Medical Devices only keeps your personal data for the time necessary to fulfil the purpose of collection or further processing, namely for 15 years as from registration of the data in MDR Eudamed.

MDR EUDAMED users will have their personal data stored as long as they hold their capacity as authorised users of the system.

MDR Art 33(6) defines the rules on personal and the retention period: Personal data shall be kept in a form which permits identification of data subjects for periods no longer than those referred to in Article 10(8).

MDR Art 10(8): “Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 56, available for the competent authorities for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market”.

Personal data of physical persons representing Competent Authorities and economic operators is kept in a form which permits identification for 15 years from the moment of their registration into MDR Eudamed.

Legitimate requests from data subjects to have their data blocked or erased will be complied with by the Commission within 60 working days as from receipt of the request.

6. How do we protect and safeguard your personal data?

All personal data in electronic format (e-mails, documents, databases, uploaded batches of data, etc.) are stored on the servers of the European Commission. All processing operations are carried out pursuant to the [Commission Decision \(EU, Euratom\) 2017/46](#) of 10 January 2017 on the security of communication and information systems in the European Commission.

In order to protect your personal data, the Commission has put in place a number of technical and organisational measures in place. Technical measures include appropriate actions to address online security, risk of data loss, alteration of data or unauthorised access, taking into consideration the risk presented by the processing and the nature of the personal data being processed. Organisational measures include restricting access to the personal data solely to

authorised persons with a legitimate need to know for the purposes of this processing operation.

7. Who has access to your personal data and to whom is it disclosed?

Access to your personal data is provided to the Commission staff responsible for carrying out this processing operation and to authorised staff according to the “need to know” principle. Such staff abide by statutory, and when required, additional confidentiality agreements.

Recipients of the data: EU Commission services, National Competent Authorities, Notified bodies, Economic operators and Sponsors for clinical investigations/performance studies, the public for the information dedicated to the public as established in the Medical Devices regulations.

EU Commission and National Competent Authorities access all data.

Notified bodies access most of the data to which they are associated as supervising entity.

Economic Operators and sponsors access their own data and the public data.

The public has only access to the personal data to be available to the public as established in the Medical Devices regulations: data about economic operators contacts and their persons responsible for regulatory compliance.

The information we collect will not be given to any third party, except to the extent and for the purpose we may be required to do so by law.

8. What are your rights and how can you exercise them?

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 are inaccurate or incomplete. Where applicable, 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. Their contact information is given under Heading 9 below.

Where you wish to exercise your rights in the context of one or several specific processing operations, please provide their description (i.e. their Record reference(s) as specified under Heading 10 below) in your request.

9. Contact information

- The Data Controller

If you would like to exercise your rights under Regulation (EU) 2018/1725, or if you have comments, questions or concerns, or if you would like to submit a complaint regarding the collection and use of your personal data, please feel free to contact the Data Controller:

European Commission

Directorate-General on Health and Food Safety (DG SANTE)
Unit SANTE.D3 – Medical Devices
200 rue de la Loi
B - 1049 Brussels
Belgium

Email address: SANTE-MED-DEV@ec.europa.eu

- **The Data Protection Officer (DPO) of the Commission**

You may contact the Data Protection Officer (DATA-PROTECTION-OFFICER@ec.europa.eu) with regard to issues related to the processing of your personal data under Regulation (EU) 2018/1725.

- **The European Data Protection Supervisor (EDPS)**

You have the right to have recourse (i.e. you can lodge a complaint) to the European Data Protection Supervisor (edps@edps.europa.eu) if you consider that your rights under Regulation (EU) 2018/1725 have been infringed as a result of the processing of your personal data by the Data Controller.

10. Where to find more detailed information?

The Commission Data Protection Officer (DPO) publishes the register of all processing operations on personal data by the Commission, which have been documented and notified to him. You may access the register via the following link: <http://ec.europa.eu/dpo-register>.

This specific processing operation has been included in the DPO's public register with the following Record reference: DPR-EC-06787.