

# EUDAMED - USER RIGHTS AND OBLIGATIONS

This document establishes User Rights and Obligations in relation to the EU database on medical devices (EUDAMED).

The purpose of EUDAMED is

- (a) to enable the public to be adequately informed about devices placed on the market, corresponding certificates issued by notified bodies, and relevant economic operators;
- (b) to enable unique identification of devices within the internal market and to facilitate their traceability;
- (c) to enable the public to be adequately informed about clinical investigations and to enable sponsors of clinical investigations to comply with their obligations;
- (d) to enable manufacturers to comply with the information obligations;
- (e) to enable the competent authorities of the Member States and the Commission to carry out their tasks relating to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 on a well-informed basis and to enhance the cooperation between them.

In order to activate a user account in EUDAMED, users must accept the rights and obligations set out in this document by ticking the box “I accept the user rights and obligations” in the EUDAMED interface.

## I. USER ACCOUNT PURPOSE

Users are granted access to EUDAMED solely for the purposes of EUDAMED specified above. In particular, EUDAMED shall not be used to perform illicit actions, or for commercial or marketing purposes.

EUDAMED’s users shall use EUDAMED in a way that corresponds to their assigned profile in accordance with the grants associated to each profile (see the User Guide chapter on User Access Management).

User access to EUDAMED may be monitored by DG SANTE, in particular to detect inappropriate use of EUDAMED. DG SANTE retains the right to suspend a user account where inappropriate use is detected.

## II. SYSTEM AVAILABILITY

EUDAMED shall be available at any time with the exception of maintenance periods. Planned maintenance will be advertised in advance.

A helpdesk is available during working hours (i.e. between 8h30 and 17h30 during Commission working days, Brussels time). Users may contact the helpdesk by sending an e-mail to:

[SANTE-EUDAMED-SUPPORT@ec.europa.eu](mailto:SANTE-EUDAMED-SUPPORT@ec.europa.eu).

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### III. DATA OWNERSHIP

EUDAMED data that have not been supplied by the user or by the organisation the user belongs to remain the property of DG SANTE and may not be copied or redistributed without prior DG SANTE authorisation, except if this is part of the granted user role.

### IV. PERSONAL DATA PROTECTION

DG SANTE is committed to protect your personal data and to respect your privacy. 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

The EUDAMED privacy statement further 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.

### V. INFORMATION SECURITY

EUDAMED users shall comply with the rules on information security set out below.

#### A. USER CREDENTIALS

- (a) The user account is personal. Users shall not share it with other persons.
- (b) Users shall protect their password and shall not share it with others. If a user realises that his/her password has been compromised, the user shall change it immediately.
- (c) Users shall not share their password with any external accounts (e.g. do not use your EUDAMED password to access your Facebook account).
- (d) Users shall not store their password in an unprotected manner (e.g. on paper or in clear text in a computer file).
- (e) Users who have several user roles/profiles must select the profile that is most appropriate to the respective actions that they intend to carry out.

#### B. USER DEVICES HANDLING

- (a) Users shall terminate their session immediately after using EUDAMED to avoid misuse of their account.
  - (b) Users shall not leave their device screens unattended while logged on to EUDAMED.
  - (c) Users shall not access EUDAMED using mobile computing devices in open spaces (e.g. public places, meeting rooms).
  - (d) Users shall not access EUDAMED while connected to untrustworthy networks.
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### C. INFORMATION HANDLING

Whenever information not available to the public is extracted from EUDAMED in electronic or paper format, the rules below must be observed. In case of users employed by, or working for, national authorities, or for the European Commission, the rules below apply without prejudice to laws or internal rules otherwise applicable to them in this context.

- (a) User shall distribute non-public information only on a need-to-know basis to authorised persons.
- (b) Users who have created non-public information records from EUDAMED shall store those records in places accessible to their target audience only (e.g. directory with access rights limited to the users with a need-to-know).
- (c) Users shall not store or transmit non-public information from EUDAMED by means of public electronic services. Prohibited public services include file storage (e.g. Dropbox), file sharing (e.g. Rapidshare), social networks (e.g. Facebook), internet forums (e.g. Reddit), unsecured e-mail (e.g. private unencrypted e-mail services) and instant messaging (e.g. Skype).
- (d) Users shall not store non-public information from EUDAMED on mobile computing devices or removable media for longer than necessary.
- (e) Extracted non-public information from EUDAMED shall be stored in encrypted format. Extracted non-public information shall not be stored on personal user devices.
- (f) Extracted non-public information from EUDAMED shall be exchanged through encrypted e-mail.
- (g) Paper copies of non-public information from EUDAMED shall be stored in a secured place Paper copies shall be destroyed once no longer needed.

DG SANTE retains the right to suspend a user account for security reasons at any time.

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