

DECLARATION ON INFORMATION SECURITY RESPONSIBILITIES IN THE CONTEXT OF THE EUROPEAN MEDICAL DEVICE DATABASE

I. GENERAL INFORMATION

Name of legal entity:

The entity is a:

- Manufacturer*
- Authorised Representative*
- Importer*
- System / Procedure Pack Producer.*

Please circle/ underline applicable type of entity. Multiple selections not permitted.

hereafter "**THE ECONOMIC OPERATOR ACTOR**" (**THE EO ACTOR**), with its legal seat at

Street:

Street number:

Postal code:

City:

Country:

II. ROLE OF THE EO ACTOR

THE EO ACTOR has an established need to use EUDAMED. User accounts will be granted privileges aligned with that need-to-use THE EO ACTOR can authorise its own staff to access EUDAMED and can manage the user accounts of its own staff

III. LOCAL ACTOR ADMINISTRATOR (LAA)

1. THE EO ACTOR designates the Local Actor Administrator (LAA)¹:

- LAA's first name:
- LAA's surname:

2. EUDAMED grants a personal user account to the LAA [in EUDAMED, all LAAs must have an EU Login account and keep their personal details up-to-date in their user account.

- Email of the LAA's EU Login account:

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3. The LAA is the point of contact regarding (1) THE EO ACTOR users and (2) information security matters.
4. Changes to the LAA must be addressed by THE EO ACTOR immediately. The EO ACTOR must have a procedure in place to guarantee that the LAA account in EUDAMED is either terminated or changed accordingly. THE EO ACTOR procedure must guarantee that there is at least one active LAA at all times in EUDAMED.
5. THE EO ACTOR registration details and the accounts of users who are acting on behalf THE EO ACTOR are administered by the LAA

IV. INFORMATION SECURITY MANAGEMENT

1. THE EO ACTOR can authorise its own staff, or where applicable, sub-contractors, to access EUDAMED in a 'user capacity' and manage their user accounts accordingly.
2. It is the responsibility of the EO ACTOR to ensure that its staff members and subcontractors which are users of the EUDAMED comply with the information security obligations set out in the present document, and that they comply with their obligations set out in the "User's Rights and Obligations", to which they must agree before accessing EUDAMED for the first time

¹ The person registering an organisation in EUDAMED automatically becomes the Local Actor Administrator (LAA.) The LAA can manage all details of its organisation in EUDAMED, and assign Local User Administrators (LUA) who can manage the user access requests for all users belonging to its organisation. It is considered good practice for an organisation to have more than one LAA at all times. At least one LAA should be employed by the organisation and not be a sub-contractor.

3. Any information security incidents or security weaknesses related to EUDAMED, should be reported immediately by the EO ACTOR LAA to the following functional mailbox:

SANTE-EUDAMED-ADMINISTRATOR@ec.europa.eu

4. THE EO ACTOR shall support DG SANTE in investigating and fixing information security incidents where there are reason to believe that his staff or subcontractors might be involved or have knowledge of.

V. USER REGISTRATION AND ADMINISTRATION OF USER ACCOUNTS

The EO ACTOR shall ensure that the creation of a user account complies with the User Registration procedures. Instructions regarding the completion of these procedures are provided, in the User Access management chapter of the User Guide. Once the procedure is completed, the user will be granted an account in EUDAMED. A similar procedure shall be applied by the EO ACTOR in case of modification of the permissions of an existing user's EUDAMED account, and in case of suspension or re-activation of an existing user's EUDAMED account.

VI. USER ACCOUNTS CURRENCY

THE EO ACTOR shall keep all user accounts up to date. The LAA should on a regular basis screen for sleeping accounts (i.e. user accounts that are inactive for a longer period of time and therefore might be obsolete), and proceed with user account termination as deemed necessary.

VII. CONFLICT OF INTEREST

For the purposes referred to in this declaration, the EO ACTOR must not hire or contract a person who has contractual relationships with other organisations that could undermine his impartiality in relation to EUDAMED. Consequently, such persons shall not be granted user rights in EUDAMED,

I, the undersigned, THE EO ACTOR, accept the rights to use the European Medical Devices Database (thereafter EUDAMED) in accordance with this document granted by the European Commission Directorate-General for Health and Food Safety (DG SANTE), and I undertake to comply with the responsibilities and obligations laid down in this document.

I confirm that I am authorised to provide the relevant information requested in this document and that the information provided is correct.

Name and first name:

Function / title:

Telephone (incl. country code):

Email:

Date and place:

[signature]