



# **EUDAMED Business Rules** **Authentication & Identity** **Management**

Production v 2.14.1  
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# Authentication & Identity Management - Business Rules

## 1 - Introduction

This "Business Rules" document contains the constraints, limitations and business rules that drive the implementation of EUDAMED.

## 2 - Purpose

This document's purpose is to provide an overview of the scope and conditions data needs to be provided to be valid information for EUDAMED.

Business rules are describing a required set of conditions who will be validated when submitting data.

## 3 - Scope

We opted to provide business processes and their detailed descriptions by module. This document refers to business rules for User Management module only.

## 4 - Change log

- No updates

## 5 - Business Rules

Summary	Status	Description
<a href="#">BR-IAM-015 : Several Eudamed accounts restrictions</a>	RESOLVED	<p>A User having a first Eudamed account for a Notified Body or the European Commission cannot have any other Eudamed account for another actor.</p> <p>A User having a first Eudamed account for a Competent Authority or Designating Authority may have another Eudamed account but only for a CA/DA within the same country. A user having already a Eudamed account for an economic operator or a sponsor may have other Eudamed accounts but only for economic operator or sponsor.</p> <p>Terminated accounts will not be included in these checks.</p>
<a href="#">BR-IAM-040 : LAA contains LUA grants</a>	RESOLVED	<p>The Local Actor Administrator (LAA) profile includes the grants of the Local User Administrator (LUA) profile.</p>
<a href="#">BR-IAM-042 : Ownership access rights</a>	RESOLVED	<p>Eudamed will consider whether data are owned by the Actor associated to the user's Eudamed account or not to determine the access rights the user may have on data in Eudamed.</p>
<a href="#">BR-IAM-047 : Subcontractor user data</a>	RESOLVED	<p>Users requesting a Eudamed Account for an actor must indicate if they work directly for this actor or if they work for a subcontractor and they must provide in the second case the name, address and contact details of their employer/company</p>
<a href="#">BR-IAM-049 : LUA/LAA own profiles assignment restriction</a>	RESOLVED	<p>Neither Local Actor Administrators (LAA) nor Local User Administrators (LUA) can add profiles to themselves</p>
<a href="#">BR-IAM-050 : There must be at least one LAA for each actor</a>	RESOLVED	<p>Terminating a Local Actor Administrator account is not allowed if this would leave the Actor without at least one Local Actor Administrator</p>
<a href="#">BR-IAM-051 : Subcontractor user restriction</a>	RESOLVED	<p>A subcontracting user can neither terminate the account of a non-subcontracting user with a Local User Administrator or a Local Actor Administrator profile, nor remove these profiles from that user</p>
<a href="#">BR-IAM-055 : Suspension account</a>	RESOLVED	<p>When a user requests a suspension, Eudamed must ensure (in the following order) that:</p> <p><i>Start date</i> and <i>End date</i> (if not empty) have valid date formats, <i>Start date</i> and <i>End date</i> (if not empty) are not in the past, <i>End date</i> (if not empty) is later than <i>Start date</i></p> <p>(Suspension feature not available in v2.0)</p>
<a href="#">BR-IAM-056 : Act only under one EUDAMED account at a time</a>	RESOLVED	<p>A user who has several accounts must select only one prior to accessing the Eudamed content</p>

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BR-IAM-058 : A EUDAMED account can be associated to only one profile per module for an Actor

RESOLVED

A EUDAMED account can be associated to only one profile per module for an Actor. Profiles are hierarchical. Profiles selected from ENUM\_IAM\_ACTOR\_PROFILES

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10 issues

