



EUDAMED Business Rules

Actor registration

Production v 2.14.1
2024



Actor Registration - Business Rules

1 - Introduction

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

2 - Purpose

This purpose of this document 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 information.

3 - Scope

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

4 - Change log

No change

5 - Business Rules

Summary	Status	Description
BR-ACT-017 : Actor ID format	RESOLVED	The format of the Actor ID (called SRN for economic operator) is CC-TT-NNN where CC is the Country code, TT is the Actor role code, and NNN is a 9 digit numerical value. This rule does not apply if the Actor type is NB or CA
BR-ACT-018 : NB ID	RESOLVED	The Actor ID of a Notified Body is equal to its NANDO identifier called Notified Body identification number in the legislation. In EUDAMED we will used NB identification numer or NB ID
BR-ACT-022 : Actor ID for CAs	RESOLVED	If an Actor is a Competent Authority or the European Commission, the numeric part of the Actor ID (NNN) is a three-digit number
BR-ACT-025 : Validating CA for EU Economic Operator	RESOLVED	The Competent Authorities entitled to validate the Registration Request of an Economic Operator established in a Country considered as part of the EU market must belong to that Country
BR-ACT-026 : Validating CA for Non-EU MF	RESOLVED	The Competent Authority entitled to validate the Registration Request of a Non-EU Manufacturer must be the Competent Authority responsible for the Authorised Representative designated by that Manufacturer in its Registration Request
BR-ACT-028 : Only one mandate between an AR and a non-EU MF	RESOLVED	Only one active or pending Mandate may exist between the same Manufacturer - Authorised Representative pair. Active or pending means in state Rejected, Submitted or Registered.
BR-ACT-029 : Conflict of interest among actors	RESOLVED	An Organisation or a user working for this organisation can represent only one Actor where it is a Notified Body or the European Commission. This to avoid a conflict of interest.
BR-ACT-031 : Access Non-Public Contact Details	RESOLVED	The Non-Public Contact Details of an Actor are accessible only to users of this Actor, to all Competent Authority users, and to all European Commission users
BR-ACT-032 : Access Notification Email Addresses	RESOLVED	The Notification Email Addresses of an Actor are hidden to all other Actors
BR-ACT-033 : Access Registration Request	RESOLVED	Data relevant to the Registration Request of an Actor, once assigned a Single Registration Number, are accessible only to the Local Actor Administrator of this Actor, to the Competent Authorities and Authorised Representatives who assessed that request, as well as to the European Commission and (if applicable) to the Competent Authority that has taken over the scope and responsibility of the one who validated the request.
BR-ACT-034 : Hide Fraud Suspected justification to requesting user	RESOLVED	If the refusal reason of a Registration Request is "Fraud suspected", only the reason "Refused" will be displayed to the user who submitted the request.
BR-ACT-037 : Economic operator validation competence	RESOLVED	Only a Competent Authority responsible for Economic operator validation (see enumeration BR-ACT-050) is allowed to approve or not approve the Registration Request of an Economic Operator

BR-ACT-042 : Actor Registration Request in Draft	RESOLVED	If an Actor Registration Request is in the Draft state, the requesting user can only edit its fields (Country and Actor type are not editable) and save it as a Draft, delete it or submit it
BR-ACT-044 : Assessment outcome of an Actor Registration Request	RESOLVED	From the moment the Actor Registration Request is in the Submitted or for non-EU manufacturer in the Verified state, the Competent Authority responsible for the Actor Registration request assessment can perform the following operations: Approve or Not Approve.. Depending on reason for non-approval may be for corrections (see BR-ACT-020) or refusal (see BR-ACT-023).
BR-ACT-045 : Archive Actor data	RESOLVED	Actor version data in the Registered state may never be deleted
BR-ACT-046 : Access draft Registration Request	RESOLVED	Only the requesting user can access an Actor Registration Request in the Draft state
BR-ACT-047 : Access submitted Non-EU MF Registration Request	RESOLVED	A Registration Request for a Non-EU Manufacturer in the Submitted state is accessible only to the Authorised Representative responsible for its review, the requesting user and the EC users
BR-ACT-048 : Verify Actor Registration Request	RESOLVED	If an Actor Registration Request for a non-EU manufacturer is in the Submitted state, the Authorised Representative associated to the request is responsible for its review and it can only request corrections (return to the requester) or accept it or indicate its disagreement in comment and pass it to the Competent Authority. Only a Competent Authority may provide the final assessment (Accept or Reject) of an Actor registration request.
BR-ACT-052 : Competent Authority legislation scope	RESOLVED	The legislation scope of the Competent Authority may be only for MD, only for IVD or for both. This scope applies to all responsibilities of this Competent Authority.
BR-ACT-054 : All CA qualifications covered	RESOLVED	A Member State (country) must have all qualifications as described in enumeration BR-ACT-050 covered by its CA(s) for each legislation. (Except for certificates and NB responsibility if there is no NB in that country)
BR-ACT-057 : One Actor ID (SRN) per actor type	RESOLVED	An Actor may have only one Actor type and one unique Actor ID (SRN for economic operator) among all actors.
BR-ACT-058 : Possible combination of CA responsibilities and Designating authority identification	RESOLVED	A Competent Authority may combine several of the responsibilities described in enumeration BR-ACT-050 except the 'responsible for Notified Bodies': that is exclusively assigned to the Designating Authorities (Competent authorities responsible for NB). The Competent Authority with the responsibility "responsible for Notified Bodies" is always a Designating Authority and will be denoted by the code "DA" instead of "CA", e.g. BE-DA-001.
BR-ACT-064 : Actor Registration Request delete/discard	RESOLVED	An Actor Registration Request may be physically deleted only if still in Draft state. Once submitted, it may only be Discarded (no physical delete).
BR-ACT-065 : Designating authority responsibilities	RESOLVED	Designating Authorities are always and only responsible for Certificates and Notified Bodies. This includes the validation of the first Local Actor Administrator access request for Notified Bodies.
BR-ACT-067 : Draft actor registration request	RESOLVED	The Actor Registration Request is in the Draft state only when the Request is created
BR-ACT-097 : No updates on terminated mandates	RESOLVED	It is not allowed to update a Terminated mandate
BR-ACT-102 : Mandate ID Format	RESOLVED	The format is "MD"- ISO Country code from Non-EU MF - ISO Country code from AR - 000001. Example: MD-AU-BE-000008
BR-ACT-107 : Terminate Registered Mandate	RESOLVED	Terminating a mandate can only be performed on mandates in status "Registered". The "Registered" mandate end date must be empty or the "Registered" mandate is not expired.
BR-ACT-108 : Mandate end date greater then start date	RESOLVED	The mandate end date if provided must be greater than the mandate start date
BR-ACT-109 : Mandate Termination date	RESOLVED	When terminating a mandate the user specifies a mandate termination date. This termination date must be greater than the mandate start date. If a mandate end date is provided, the mandate termination date must occur before it.
BR-ACT-111 : Mandate Versioning	RESOLVED	Create a new mandate means creating a new mandate with version 1 in status "Submitted". A new version of a mandate can only be created for a mandate in status "Registered" by performing the "Create new version" use case.
BR-ACT-112 : Deleting a mandate	RESOLVED	Only mandates in state "Submitted" for the first time can be deleted. Deleted means removing the record from the system/Database.
BR-ACT-113 : Reject Mandate when new actor registration request is rejected	RESOLVED	When a new actor registration request is not approved, the mandate included in that request will also be considered as rejected in EUDAMED.
BR-ACT-115 : GPS Format	RESOLVED	The GPS is stored as a decimal format in two optional fields Longitude and Latitude. The range for the Latitude field is -90 and 90. The range for the Longitude field is -180 and 180. Both fields follow the format: -999/0(14).

BR-ACT-117 : PDF file restriction for all documents	RESOLVED	PDF file restriction for all documents part of the actor registration												
BR-ACT-118 : A Non-EU PR can select a CA for validation from any EU country	RESOLVED	A Non-EU PR (System and/or procedure pack producer) can be from any country. without a need for an Authorised representative if outside EU. A EU PR must select a CA of its country, where a non-EU PR must select a CA from any EU country.												
BR-ACT-119 : Organisation name is a language specific field containing the "All languages"	RESOLVED	An organisation name with language "All languages" indicates that this value is language independent												
BR-ACT-120 : The abbreviated name is a language specific field containing the "All languages"	RESOLVED	An abbreviated name with language "All languages" indicates that this value is language independent												
BR-ACT-124 : At least one CA for each country should have the EO validator responsibility	RESOLVED	A CA with economic operator validation responsibility must always exists and be active for each member state.												
BR-ACT-125 : Only EC and CA can see the NB contact persons, Assessment documents and DA imported from NANDO	RESOLVED	Only EC and CA can see the NB contact persons, Assessment documents and DA imported from NANDO. This information is not publicly available on NANDO												
BR-ACT-126 : Importer link date restrictions	RESOLVED	When updating an importer - non-EU MF link, the end date must be greater than the start date. If the present day is not within the interval selected, the link is considered inactive.												
BR-ACT-128: When a LAA want to change the CA, he should not be able to choose the same CA	RESOLVED	the system should prevent the LAA who want to change its CA, to choose the same CA												
BR-ACT-131: Access Points configuration limitations per actor	RESOLVED	<table border="1"> <thead> <tr> <th>ACTORS</th> <th>Internal AP</th> <th>External AP</th> <th>Total APs</th> </tr> </thead> <tbody> <tr> <td>EOs</td> <td>max 1</td> <td>max 2</td> <td>max 2</td> </tr> <tr> <td>SAs</td> <td>max 1</td> <td>none</td> <td>max 1</td> </tr> </tbody> </table> <p>Where:</p> <ul style="list-style-type: none"> • EOs = Economic Operators: MFs, SPPPs, ARs, IMPs • SAs = Supervising authorities: CAs, DAs, NBs • Internal AP = Access Point owned by the Actor • External AP = Access Point not owned by the logged in Actor (could be 3rd Party or owned by another Eudamed Actor) 	ACTORS	Internal AP	External AP	Total APs	EOs	max 1	max 2	max 2	SAs	max 1	none	max 1
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BR-ACT-132 a M2M service can only be accessed through one Access Point Link	RESOLVED	While certain Actor types are entitled to have more than one Access point link, it is only permitted to link a M2M service to one. In other words, if the Actors Service "Search for Actor" is attached to Access Point Link 1 it cannot also be attached to access point link 2												
BR-ACT-133 Valid Access Points to link to	RESOLVED	When linking to an existing Access Point using a Party ID, the access point you wish to link to must have been marked as able to use by other actors: The field "May this access point be used by other Actor(s)" must have been set to "Yes" when the access point was created. If this was not the case, the validation of the access point will always say "Access Point not found" even if the Party ID does exist												
BR-DTX-ACT-001 : At least one search criteria	RESOLVED	At least one search criteria needs to be provided in for downloading registered actors.												
BR-DTX-ACT-002 : Download xml list of registered actor criteria	RESOLVED	A user must be able to download a list of registered actors using the following filter criteria: <ul style="list-style-type: none"> • Actor::Actor.actorCode • Actor::Actor.Type(instanceof*) • Actor::Actor.Organisation.Coordinates.Address.Country • Version • Version Date 												
BR-DTX-ACT-003 : Versioned Registered Actor download criteria	RESOLVED	A user should be able to download all / specific versions of an single Actor when sets criteria Actor::Actor.Version. <ul style="list-style-type: none"> • applicable only in combination of other criteria, return only one actor instance - if gt 0, means to request all versions for a specific actor; <i>return all the actor versions grater than the specified version number</i> 												

BR-DTX-ACT-005 : Registered Actor download sort list criteria - unique actor code number	RESOLVED	Registered Actor download xml should contain entites having a unique (EUDAMED generated) actorCode field value {Actor.actorCode}, except the case when multiple version of the same object are requested.
BR-DTX-ACT-006 : Registered Actor download service and payload definition	RESOLVED	Registered Actor download object list provided should be paginated / versioned list of {Actor} objects in xml format.
BR-DTX-ACT-007 : Registered Actor download default object version	RESOLVED	Registered Actor download object list should contain, by default, the latest version of {Actor} objects, except the case when Version criteria is selected (in the service request).
BR-DTX-ACT-008 : Registered Actor download object list pagination	RESOLVED	Registered Actor download object list should be paginated with max of 300 items per page.
BR-DTX-ACT-009 : Registered Actor download object type	RESOLVED	An actor object should be of type {Actor}.
BR-DTX-ACT-012 : Registered Actor download country criteria	RESOLVED	The search criteria country code can only be used in combination with the actor role (Economic Operators). Release 1.3 onwards: If country code is not provided, the system will return results from all countries.
BR-DTX-ACT-014 : Registered Actor download version date criteria	RESOLVED	When providing a version date criteria the response will contain all the actor entities that have been created / update since that date. Version date must be combined with actor role. (Country code requirement removed in v1.3 release)
BR-DTX-ACT-015 : "AND" condition between search criteria	RESOLVED	There is an "AND" condition between provided search fields for downloading registered actors.
BR-DTX-ACT-016 : Full SRN, no wildcards for search criteria	RESOLVED	SRN should be the entire SRN (no wildcards) as a search criteria for downloading registered actors.
BR-DTX-ACT-017 : Latest version when searched on SRN only	RESOLVED	By default only the latest version of the actor will be returned when searched on SRN only.
BR-DTX-ACT-018 : Latest version when no version number or version date	RESOLVED	If "version number" or "version date" are not provided, only the latest version is returned.
BR-DTX-ACT-019 : Version date cannot be combined with Version number	RESOLVED	Version date cannot be combined with Version number.
BR-DTX-ACT-020 : Download xml list of actor registration requests to be assessed	RESOLVED	A user as CA must be able to download a list of actor registration requests that belongs to the current {CA Validator}
BR-DTX-ACT-021 : Actor registration request download security list criteria	RESOLVED	Actor registration requests to be downloaded must contains: <ul style="list-style-type: none"> state = SUBMITTED for EU EOs state = VERIFIED for NON EU Manufacturers requester actor CA code should match the validating CA code.
BR-DTX-ACT-023 : Actor registration request unique application number	RESOLVED	Actor registration request must be uniquely identified through an generated number (EUDAMED generated) {ActorRegistration.applicationID}.
BR-DTX-ACT-024 : Actor registration request service and payload definition	RESOLVED	Actor registration request list should be a list of {ActorRegistrationRequest} objects in xml format.
BR-DTX-ACT-026 : Actor registration request previous decision	RESOLVED	An actor registration request should be of type {ActorRegistrationCorrectionDecision} if any.
BR-DTX-ACT-027 : Only one value for a search criteria	RESOLVED	Only one value can be provided for a search criteria. Providing a list of values within one search criteria will not be allowed either.
BR-DTX-ACT-030 : Actor code not available during registration	RESOLVED	During the actor registration request procedure the actor code is not yet available. It will be generated when the request is approved by the Competent Authority. During this process the actor code has the value "NA" and once assessed it will display the actor code (SRN)
BR-DTX-ACT-031 : PRRCPersons only available for MF and AR	RESOLVED	PRRCPersons are only required and provided for Manufacturers and Authorised Representatives.

BR-DTX-ACT-032 : Mandates information for a NON EU Manufacturer	RESOLVED	The Authorised representative for a NON-EU Manufacturer is stored within the mandate information. Mandate information is only exported for the NON EU Manufacturer
BR-DTX-ACT-033 : Mandate vigilance delegated to AR	RESOLVED	By default the mandate management for vigilance is not delegated by the Manufacturer to the Authorised Representative. The DTX export value is FALSE.
BR-DTX-ACT-034 : Pending Actor Registrations object list pagination	RESOLVED	Pending Actor Registrations object list should be paginated with max of 300 items per page.
BR-DTX-ACT-035 : Search on initial submission date returns all the actor registration requests that have been created / update since the provided date	RESOLVED	Search on initial submission date returns all the actor registration requests that have been created / update since the provided date
BR-DTX-ACT-036 : No wildcards on Application ID search criteria	RESOLVED	No wildcards on Application ID search criteria is allowed, only exact match.
BR-DTX-ACT-040 : Upload xml list of actor registration assessment processed	RESOLVED	CA{CA VALIDATOR} user must be able to upload a list of actor registration assessments that belongs to the current {CA VALIDATOR} user.
BR-DTX-ACT-042 : Actor registration assessment upload security validation criteria	RESOLVED	Actor registration assessment to be uploaded must have: <ul style="list-style-type: none"> • one of the following decision type: refusal, approval or correction; • requester actor CA code should match the validating CA code; • restate the actor address and actor organisation name;
BR-DTX-ACT-043 : Actor registration assessment service and payload definition	RESOLVED	Actor registration assessment list should contain unpaginated / unversioned list of {ActorRegistrationResponse} objects in xml format.
BR-DTX-ACT-047 : Actor registration assessment upload validation criteria on registration status	RESOLVED	An upload of an actor request assessment must be validated against the current application status. An error must be triggered if detected a conflict registration request decision types or status
BR-DTX-ACT-048 : Actor registration assessment data processing feedback	RESOLVED	A feedback/result of the processing of the upload of the actor registration assessment processing status in EUDAMED should be available.
BR-DTX-ACT-049 : Actor Registration assessment fields part of validation check	RESOLVED	<ul style="list-style-type: none"> • Application ID • Role • Name • City • Post Code • Country <p>If one field is different then the Actor data from the request, the Assessment is INVALID</p>
BR-DTX-ACT-50: If party id already generated for actor, cannot generate again for same actor	RESOLVED	

80 issues

