# Notified Bodies & Certificates - Business Rules - 2.8

## 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 Certificate module business rules only.

## 4 - Changelog

# 5 - Business Rules

| Summary | Status | Description |
|---|---|---|
| BR-CRF-001 : Registration of core certificate information | RESOLVED | When registering an issued certificate, the following information are mandatory to be completed:<br>- Notified Body;<br>- (where applicable) Manufacturer;<br>- (where applicable) System/Procedure Pack Producer;<br>- (where applicable) Authorised Representative(s);<br>- Applicable Regulation, Certificate Type, Certificate Number<br>- (where applicable, if applicable) Certificate Revision number;<br>- Date of issue, Starting certificate validity date and Expiry date;<br>- (where applicable) the Devices in the scope of the certificate;<br>- (where applicable) the Device Groups in the scope of the certificate;<br>- (if applicable) conditions for or limitations/restrictions to the validity of the certificate;<br>- Certificate document(s) in the official language(s) that it has been issued.<br><br>*Notes:*<br>*- 'where applicable' means that additional business rules define the optionality of the referred information*<br>*- 'if applicable' means that the information must be provided if it exists* |

| | | |
|---|---|---|
| BR-CRF-002 : Registration of core refused certificate information | RESOLVED | When registering a refused certificate the following information shall be provided:<br>- Notified body;<br>- (where applicable) Manufacturer;<br>- (where applicable) System/Procedure Pack Producer;<br>- (where applicable) Authorised Representative(s)<br>- Certificate applicable legislation, certificate type;<br>- Date of refusal;<br>- Reason for refusal;<br>- An indication if it contains sterilised system/procedure packs;<br>- An indication if it contains custom made class III devices;<br>- The scope of the refused certificate;<br>Devices and/or device groups. |
| BR-CRF-005 : Singularity of certificate number | RESOLVED | Each new issued or re-issued certificate shall have a unique certificate identification (Certificate number + revision number) per notified body. |
| BR-CRF-006 : Unicity of notified body | RESOLVED | A certificate shall be associated to one and only one notified body. |
| BR-CRF-007 : Identification of notified body | RESOLVED | The notified body shall be identified by its NB identification number (assigned by NANDO). |
| BR-CRF-008 : Notified body validity | RESOLVED | To register a certificate or a CECP in Eudamed the NB must be designated (active). |
| BR-CRF-009 : Unicity of manufacturer | RESOLVED | A certificate registration, application registration or CECP registration shall be associated to one and only one manufacturer. |
| BR-CRF-010 : Identification of manufacturer | RESOLVED | The manufacturer shall be identified by its single registration number (SRN). |
| BR-CRF-011 : Valid registration and validity of a manufacturer | RESOLVED | The manufacturer of a certificate, must be registered as an actor of type manufacturer and its registration must be valid at the date of registration of the certificate and/or CECP in Eudamed. |
| BR-CRF-012 : Optionality of authorised representative(s) in the certificate information | RESOLVED | If the manufacturer in a certificate is a **non EU manufacturer then it is mandatory to provide the authorised representative(s)** responsible for the devices covered by the certificate.<br>In case of an **EU manufacturer no authorised representatives** shall be provided. |
| BR-CRF-013 : Multiplicity of authorised representative in the certificate information | RESOLVED | For the following certificate types for non-EU manufacturer **one and only one** authorised representative is required:<br>• - (MDR) EU Technical Documentation certificate (Annex IX Chapter II);<br>• - (MDR) EU Type Examination certificate (Annex X);<br>• - (MDR) EU Product verification certificate (Annex XI Part B);<br>• - (IVDR) EU Technical Documentation certificate (Annex IX Chapter II);<br>• - (IVDR) EU Type Examination certificate (Annex X).<br>For the following certificate types for a non-EU manufacturer **at least one** authorised representative is required:<br>• - (MDR) EU Quality Management System certificate (Annex IX Chapter I);<br>• - (MDR) EU Quality Assurance certificate (Annex XI Part A);<br>• - (IVDR) EU Quality Management System certificate (Annex IX Chapter I);<br>• - (IVDR) EU Production Quality Assurance certificate (Annex XI). |
| BR-CRF-014 : Identification of authorised representative(s) in the certificate information | RESOLVED | Each authorised representative related to a certificate shall be identified by its single registration number (SRN). |
| BR-CRF-015 : Valid registration and validity of an authorised representative | RESOLVED | The authorised representative in a certificate and/or CECP registration, must be registered as an actor of type authorised representative and its registration must be valid at the date of registration of the certificate and/or CECP in Eudamed. |
| BR-CRF-016 : Authorised representative mandates must be valid at registration of the certificate | RESOLVED | For each authorised representative in a certificate, at registration of the certificate in Eudamed there must be valid and active mandates linking the authorised representative with the manufacturer of the certificate. |

| | | |
|---|---|---|
| BR-CRF-017 : Indication on inclusion of sterilised system/procedure packs | RESOLVED | An indication as to whether the certificate includes sterilized system/procedure packs, shall be provided as follows:<br><br>- The certificate has no sterilised system/procedure packs;<br><br>- The certificate, amongst other, contains devices that are sterilised system/procedure packs;<br><br>- The certificate contains only sterilised system/procedure packs. |
| BR-CRF-018 : Optionality of indication on inclusion of sterilised system/procedure packs | RESOLVED | The indicator on inclusion of sterilised system/procedure packs **applies only to** the MDR certificate types:<br><br>• EU Quality Management System certificate (Annex IX Chapter I)<br>• EU Quality Assurance certificate (Annex XI Part A). |
| BR-CRF-019 : Indication on inclusion of custom made class III implantable device | RESOLVED | An indication as to whether the certificate includes custom-made class III implantable device(s) (MDR Art 52.8), as follows:<br><br>• The certificate has no custom-made class III implantable device(s);<br>• The certificate, amongst other, contains devices that are custom-made class III implantable device(s)<br>• The certificate contains only custom-made class III implantable device(s). |
| BR-CRF-020 : Optionality of indication on inclusion of custom made class III implantable device | RESOLVED | The indicator on inclusion of custom made class III implantable device **applies only to** the MDR certificate types:<br><br>• EU Quality Management System certificate (Annex IX Chapter I)<br>• EU Quality Assurance certificate (Annex XI Part A). |
| BR-CRF-021 : Issue date may not be in the future | RESOLVED | The date of issue of the certificate must not be in the future. |
| BR-CRF-022 : Starting certificate validity date is equal or greater than the date of issue | RESOLVED | The starting certificate validity date of the certificate must be equal or must be greater than its date of issue. |
| BR-CRF-023 : Certificate may be issued up to 3 months before its starting certificate validity date | RESOLVED | The starting certificate validity date must be within 3 calendar months after the date of issue. |
| BR-CRF-024 : Expiry date is after the date of issue and certificate validity date | RESOLVED | The expiry date of the certificate must be after the Date of issue date and Starting certificate validity date. |
| BR-CRF-025 : Expiry date is in the future | RESOLVED | The expiry date of the certificate must be greater than the date of submission of the certificate in MDR Eudamed. |
| BR-CRF-026 : Certificate validity period max up to 5 years | RESOLVED | A certificate can be issued for a maximum validity period of 5 calendar years from the starting certificate validity date. |
| BR-CRF-027 : Device risk class | RESOLVED | The risk class can be any of the following:<br><br>• III,<br>• IIb,<br>• IIa,<br>• I,<br>• D,<br>• C,<br>• B,<br>• A. |

| | | |
|---|---|---|
| BR-CRF-029 : Applicable device risk classes per legislation (MDR/IVDR) and certificate type | RESOLVED | Each certificate type can contain devices of specific risk class(es) as per the rules below. |

| Regulation | Certificate type | Possible risk class (es) |
|---|---|---|
| MDR | EU Quality Management System certificate (Annex IX Chapter I) | III, IIb, IIa, I |
| MDR | EU Technical Documentation certificate (Annex IX Chapter II) | III, IIb |
| MDR | EU Type Examination certificate (Annex X) | III, IIb |
| MDR | EU Quality Assurance certificate (Annex XI Part A) | III, IIb, IIa, I |
| MDR | EU Product verification certificate (Annex XI Part B) | III, IIb, IIa |
| | | |
| IVDR | EU Quality Management System certificate (Annex I Chapter I) | D, C, B, A |
| IVDR | EU Technical Documentation certificate (Annex I Chapter II) | D, C, B |
| IVDR | EU Type Examination certificate (Annex X) | D, C |
| IVDR | EU Production Quality Assurance certificate (Annex XI) | D, C, A |

| | | |
|---|---|---|
| BR-CRF-031 : Optionality of certificate languages | RESOLVED | It is mandatory to identify in which language(s) the certificate is entered in MDR Eudamed. |
| BR-CRF-032 : Certificate document (s) and certificate language(s) | RESOLVED | An electronic version of the paper certificate(s) shall be provided, in all the certificate languages identified. There will be the possibility to upload multiple electronic versions specifying the language of the electronic document. |
| BR-CRF-033 : File format of certificate document | RESOLVED | The electronic certificate document(s) shall be provided in PDF. |
| BR-CRF-035 : Certificate refusal reason optionality | RESOLVED | The indication of the reason for certificate refusal is mandatory for refused certificates. |
| BR-CRF-036 : Optionality of comment for application refusal/withdrawal reason | RESOLVED | It is mandatory to provide comment in text if reason for refusal is 'Other' in all decision languages. |
| BR-CRF-038 : Certificate identification | RESOLVED | Certificate ID is a unique identification of a certificate version, composed of the NB identification number, certificate number and if applicable certificate revision number. |
| BR-CRF-039 : Mandatory certificate scope | RESOLVED | It is mandatory to identify the certificate scope with at least one device or one device group except when certificate scope is identified with SPP sterilisation only. |
| BR-CRF-042 : Identification of device scope in product certificates | RESOLVED | The scope of MDR or IVDR product certificates<br>• (MDR) EU Technical Documentation certificate (Annex IX Chapter II),<br>• (MDR) EU Type Examination certificate (Annex X),<br>• (MDR) EU Product verification certificate (Annex XI Part B),<br>• (IVDR) EU Technical Documentation certificate (Annex IX Chapter II),<br>• (IVDR) EU Type Examination certificate (Annex X))<br>shall be specified by providing the Basic UDI-DI, device type and intended purpose of the device. |
| BR-CRF-044 : Device type and horizontal codes | RESOLVED | Notified Body must select one code related to the device type and they may select several horizontal codes related to the device referenced in the certificate being registered. |
| BR-CRF-045 : Basic UDI-DI in the scope of a certificate must be registered in MDR Eudamed | RESOLVED | When the scope of a certificate includes a Basic UDI-DI it must have been already submitted by the manufacturer in MDR Eudamed. |
| BR-CRF-046 : Basic UDI-DI and UDI-DI data applicable at the issue date of certificate | RESOLVED | With respect to the certificate, the information on the Basic UDI-DI information shall be deemed to be those applicable at the date of registration of the certificate. |
| BR-CRF-048 : Characteristics of class I devices included in the scope of a certificate | RESOLVED | When the scope of a certificate includes a class I device, the device must be **"placed on the market in sterile condition"** or **"with a measuring function"** or **"re-usable surgical instrument"** or combinations thereof. |
| BR-CRF-049 : Name and address of the notified body | RESOLVED | The notified body number, name and country in the certificate shall be deemed to be the one that is valid at the date of issue of the certificate. |

| | | |
|---|---|---|
| BR-CRF-050 : Name and address of the manufacturer | RESOLVED | The name and address of the manufacturer in the certificate shall be deemed to be the one that is valid at the date of issue of the certificate. |
| BR-CRF-051 : Name and address of the authorised representative | RESOLVED | The name and address of the authorised representative in a certificate shall be the one that is valid at the date of validity of the certificate. |
| BR-CRF-052 : Date of issue of the certificate is mandatory | RESOLVED | Date of issue of the certificate is mandatory |
| BR-CRF-054 : Starting certificate validity date of the certificate is mandatory | RESOLVED | Starting certificate validity date of the certificate is mandatory |
| BR-CRF-056 : Date of expiry is mandatory | RESOLVED | Date of expiry is mandatory |
| BR-CRF-057 : Mandatory certificate languages | RESOLVED | The languages of the certificate shall include **at least** the languages required by the Member State where the NB is established and/or the language required by the NB (Art 56.1) |
| BR-CRF-060 : Conditions (prior certificate status) for imposing restrictions to a certificate | RESOLVED | A certificate can be restricted (its status becomes 'Restricted') only if its current status is 'Issued', 'Re-instated', 'Amended', 'Supplemented', or 'Re-issued'. |
| BR-CRF-061 : Conditions (prior certificate status) for suspending a certificate | RESOLVED | A certificate can be suspended (its status becomes 'Suspended') only if its current status is 'Issued', 'Re-instated', 'Amended', 'Supplemented', 'Restricted', 'Suspended' or 'Re-issued'. |
| BR-CRF-062 : Conditions (prior certificate status) for re-instating a certificate | RESOLVED | A certificate can be re-instated (its status becomes 'Re-instated') only if its current status is 'Suspended'. |
| BR-CRF-063 : Conditions (prior certificate status) for withdrawing a certificate | RESOLVED | A certificate can be withdrawn (its status becomes 'Withdrawn') only if its current status is 'Issued', 'Restricted', 'Suspended', 'Re-instated', 'Amended', 'Supplemented' or 'Re-issued'. |
| BR-CRF-064 : Conditions (prior certificate status) for amending a certificate | RESOLVED | A certificate can be amended (its status becomes 'Amended') only if its current status is 'Issued', 'Restricted', 'Re-instated', 'Supplemented', 'Amended' or 'Re-issue'. |
| BR-CRF-065 : Conditions (prior certificate status) for supplementing a certificate | RESOLVED | A certificate can be supplemented (its status becomes 'Supplemented') only if its current status is 'Issued', 'Restricted', 'Re-instated', 'Amended', 'Supplemented' or 'Re-issued'. |
| BR-CRF-066 : Conditions (prior certificate status) for the re-issue of a certificate | RESOLVED | A certificate can be re-issued (its status becomes 'Re-issued') only if its current status is 'Issued', 'Restricted', 'Re-instated', 'Amended', 'Supplemented' or 'Re-issued'. |
| BR-CRF-067 : Conditions (prior certificate status) for cancellation of a certificate | RESOLVED | A certificate can be cancelled (its status becomes 'Cancelled (by MF)') only if its current status is 'Issued', 'Restricted', 'Re-instated', 'Amended', 'Supplemented' or 'Re-issued'. |
| BR-CRF-068 : Conditions (prior certificate status) for discarding a certificate version | RESOLVED | Only the last current version of a certificate can be set as 'Discarded' whatever its status is but 'Discarded' (technical status used for correction). |
| BR-CRF-069 : Certificate status becomes 'Discarded' if a registered certificate is discarded | RESOLVED | When a registered certificate is discarded then the certificate is set at the 'Discarded' state. |
| BR-CRF-070 : Registration of a new certificate in the 'Issued' status | RESOLVED | Issued shall be only the status of a newly registered certificate, with no previous versions. |
| BR-CRF-071 : Final status 'Withdrawn' or 'Cancelled by MF' | RESOLVED | A certificate cannot be further updated if it is withdrawn (certificate status is 'Withdrawn') or cancelled (certificate status is 'Cancelled by MF'). |
| BR-CRF-075 : Application reference usage | RESOLVED | The “Application- ID” is required to be assigned by the NB for any application request for certification it receives. This Application ID will be essential to have in Eudamed for registration of application refusal or withdrawal but as well for NOT-FOLLOWED CECP and refused certificates allowing linking. |
| BR-CRF-076 : Certificate identification check | RESOLVED | When registering a new issued or re-issued certificate the same NB may not have any other certificate in any status 'Issued' or 'Re-issued' or 'Amended' or 'Supplemented' or 'Restricted' or 'Re-instated' or 'Suspended' or 'Withdrawn' or 'Cancelled by MF' with the same 'Date of Issue', and 'Certificate number' + 'Revision number' (including the case that the 'Revision number' is left empty). |
| BR-CRF-077 : Populating Basic UDI-DI(s) when registering an SS(C)P | RESOLVED | When registering an SS(C)P within the registration/re-issuing of a certificate of type product then the system will automatically populate the list of Basic UDI-DI(s) that were provided in "Provide device data" page. Notified Body can multi-select Basic UDI-DI(s) to be linked to the SS(C)P being registered. |

| | | |
|---|---|---|
| BR-CRF-080 : Visibility of certificate version with 'Discarded' state | RESOLVED | Certificate versions with '**Discarded**' state in Eudamed are only visible to the **CAs**, the **EC** and the concerned **NB**.<br><br>These certificates are considered to contain errors. |
| BR-CRF-081 : Accessibility of certificate version with 'Draft' state | RESOLVED | Only the NB owner of the certificate may access a 'Draft' certificate version. |
| BR-CRF-082 : Visibility/Accessibility of certificate version with 'Registered' state | RESOLVED | All actors and the public may view all information in Eudamed for 'Registered' certificate versions.<br><br>Only the NB owner of the certificate version may set the last (current) certificate version to 'Discarded' or associate it to a new certificate version. |
| BR-CRF-083 : Delete a 'Draft' certificate | RESOLVED | When deleting a certificate in state 'Draft' the certificate will be removed from Eudamed |
| BR-CRF-084 : MDR rules for confirming devices | RESOLVED | For the following MDR certificate types and their risk classes, devices need to be confirmed by the NB when registering an issued certificate:<br><br>• EU type-examination certificate (Annex X) : Class III , Class IIb<br>• EU product verification certificate (Annex XI Part B) :Class III , Class IIb<br>• EU technical documentation assessment certificate (Annex IX Chapter II) : Class III , Class IIb + implantable + NON sutures/staples/dental fillings/… |
| BR-CRF-085 : IVDR rules for confirming devices | RESOLVED | For the following IVDR certificate types and their risk classes, devices need to be confirmed by the NB when registering an issued certificate:<br><br>EU technical documentation assessment certificate (Annex IX Chapter II) :<br><br>• Class D ,<br>• Class C + Self testing and/or near patient testing devices,<br>• Class B + Self testing and/or near patient testing devices,<br><br>EU type-examination certificate (Annex X) :<br><br>• Class D ,<br>• Class C |
| BR-CRF-104 : Notified Body Subsidiaries List must be a PDF document | RESOLVED | In order to upload into Eudamed the Notified Body Subsidiaries List, this list must be in a PDF document format. |
| BR-CRF-105 : Intended purpose of a device in certificates of type product | RESOLVED | The intended purpose of a device must be provided in all certificate languages when registering a certificate of type product. |
| BR-CRF-108 : Systems and/or Procedure pack group(s) applicability | RESOLVED | Systems and/or Procedure pack group(s) are applicable for the **Regulation (EU) 2017/745 on medical devices** within the following quality type certificates:<br><br>• EU Quality Management System certificate (Annex IX Chapter I)<br>• EU Quality Assurance certificate (Annex XI Part A) |
| BR-CRF-109 : A certificate can reference devices produced by the same manufacturer only | RESOLVED | EUDAMED will allow referencing only Basic UDI-DI(s) registered by the same manufacturer that is referenced in the certificate being registered. |
| BR-CRF-110 : Maximum number of Basic UDI-DI in the scope of product certificates | RESOLVED | The scope of the product certificates types<br><br>• (MDR) EU Technical Documentation certificate (Annex IX Chapter II),<br>• (MDR) EU Type Examination certificate (Annex X),<br>• (MDR) EU Product verification certificate (Annex XI Part B),<br>• (IVDR) EU Technical Documentation certificate (Annex IX Chapter II),<br>• (IVDR) EU Type Examination certificate (Annex X))<br><br>can include **more than one** Basic UDI-DI. |
| BR-CRF-111 : Application reference number is unique per Notified Body | RESOLVED | Application reference number is a unique identification number given by the notified body to the application.<br><br>Notified Body ID number and Application reference number together must be overall unique. |
| BR-CRF-116 : Applicability of Special Device Type attributes | RESOLVED | Special device type attributes are applicable only to devices within quality type of certificates. Special device type attributes are not applicable for System and/or Procedure Pack Sterilisation. |

BR-CRF-117 : Device group(s) may include more than one risk class

RESOLVED

A device group must include **at least one** risk class.

BR-CRF-118 : Provision of Summary of Safety and Clinical Performance (SSCP) under MDR regulation

RESOLVED

For the following combinations of certificate type, device risk class, device group risk class under Regulation (EU) 2017/745 on Medical Devices a Summary of Safety and Clinical Performance (SSCP) is required:

| Certificate type | Basic UDI-DI risk class and characteristics | Device group risk class | Device name or Device reference/catalogue number |
|---|---|---|---|
| EU Quality Management System certificate (Annex IX Chapter I) | Class IIb (sutures/staples /dental fillings)<br>Class IIa (implantable) | Class IIb<br>Class IIa | Class IIb<br>Class IIa |
| EU Technical Documentation certificate (Annex IX Chapter II) | Class III<br>Class IIb (implantable NON sutures/staples /dental fillings) | | |
| EU Type Examination certificate (Annex X) | Class III<br>Class IIb (implantable sutures/staples/dental fillings)<br>Class IIb (implantable NON sutures/staples /dental fillings) | | |
| EU Product verification certificate (Annex XI Part B) | Class IIa (implantable) | | |
| EU Quality Assurance certificate (Annex XI Part A) | Class IIa (implantable) | Class IIa | Class IIa |

BR-CRF-119 : Provision of Summary of Safety and Performance (SSP) under IVDR regulation

RESOLVED

For the following combinations of certificate type, device risk class, device group risk class under the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices a Summary of Safety and Performance (SSP) is required:

| Certificate type | Device risk class | Device group risk class |
|---|---|---|
| EU Quality Management System certificate (Annex IX Chapter I) | Class C NON (Self/near patient testing devices and companion diagnostics) | Class C |
| EU Technical Documentation certificate (Annex IX Chapter II) | Class D<br>Class C (Self/near patient testing devices and/or companion diagnostics) | |
| EU Type Examination certificate (Annex X) | Class D<br>Class C | |

BR-CRF-121 : Reference to preceding certificate

RESOLVED

An issued certificate, that was amended, supplemented, restricted or re-issued references a / the preceding certificate.

BR-CRF-122 : Different certificate number and/or revision number from the preceding certificate

RESOLVED

An amended, restricted, supplemented or re-issued certificate must have its (certificate number and/or revision number per Notified Body ID) different from its preceding certificate' certificate number and/or revision number.

| | | |
|---|---|---|
| BR-CRF-123 : Possibility to merge two or more certificates of type quality when re-issuing | RESOLVED | When re-issuing the following certificate types:<br>• (MDR) EU Quality Management System certificate (Annex IX Chapter I)<br>• (MDR) EU Quality Assurance certificate (Annex XI Part A)<br>• (IVDR) EU Quality Management System certificate (Annex IX Chapter I)<br>• (IVDR) EU Production Quality Assurance certificate (Annex XI)<br><br>it will be possible to merge two or more certificates that already exists in EUDAMED. This possibility will be given when the following conditions are met:<br>• Certificates are in state REGISTERED<br>• Certificates **are not** in one of the following statuses: SUSPENDED, WITHDRAWN, CANCELLED BY MF<br>• Certificates are of the same type;<br>  • In case of SPP applicable must be the same type of SPP (SPP only or SPP + Devices)<br>• Certificates are registered by the same Notified Body;<br>• Certificates references the same Manufacturer (same SRN);<br>• Certificates references the same SPP Producer (same SRN) (if SPP is applicable). |
| BR-CRF-126 : Certificate and/or revision number cannot be changed when performing a decision operation over an issued certificate | RESOLVED | In case of SUSPEND, RE-INSTATE, WITHDRAW or CANCELL BY MF (activities which refer to a decision taken with respect to a specific certificate<br>but do not touch the certificate as such), the certificate number as well as the revision number cannot be changed. |
| BR-CRF-128 : No further updates for an expired certificate | RESOLVED | The system will not allow any updates on a certificate which expiry date is before the current system date. |
| BR-CRF-129 : Mandatory new certificate number when revision number does not exist | RESOLVED | When AMENDING, SUPPLEMENTING, RESTRICTING or RE-ISSUING a certificate that has no revision number a new certificate number must be used as otherwise two certificate documents with different content but identical certificate numbers would exist. |
| BR-CRF-130 : Mandatory provision of Date of Issue | RESOLVED | Date of issue is mandatory to be provided when ISSUING, AMENDING, SUPPLEMENTING, RESTRICTING or RE-ISSUING a certificate. |
| BR-CRF-131 : Date of Issue cannot be changed when drawing a decision over a certificate | RESOLVED | In case of SUSPENDING, RE-INSTATING, WITHDRAWING or CANCELLING BY MF (activities which refer to a decision taken with respect to a specific certificate<br>but do not touch the certificate as such), the issue date cannot be changed. |
| BR-CRF-133 : Decision date must be provided when drawing a decision over a certificate | RESOLVED | Decision date must be provided in case of SUSPENDING, RE-INSTATING, WITHDRAWING or CANCELLING BY MF. Decision date is greater or equal than preceding certificate decision date and cannot exceed preceding certificate Expiry date. |
| BR-CRF-134 : Starting decision applicability date must not exceed 3 calendar months after the decision date | RESOLVED | Starting decision applicability date must not exceed 3 calendar months after the decision date. Starting decision applicability date is greater or equal to decision date. Starting decision applicability date cannot be earlier than the Starting certificate validity date and cannot exceed certificate Expiry date. |
| BR-CRF-135 : Expiry date may only be shortened when restricting a certificate | RESOLVED | In case of RESTRICTING a certificate the expiry date may only be shortened but not extended. The expiry date cannot exceed the preceding certificate's expiry date. |
| BR-CRF-136 : A new certificate document must be uploaded when amending, supplementing, restricting or re-issuing a certificate | RESOLVED | A new electronic PDF format certificate document must be uploaded when amending, supplementing, restricting or re-issuing a certificate. The new electronic document must cover all the languages in which the certificate is. |
| BR-CRF-137 : A decision document must be uploaded when suspending, re-instating, withdrawing a certificate | RESOLVED | An electronic PDF format decision document must be uploaded when suspending, re-instating, withdrawing a certificate. Uploading more than one document (PDF format) will be allowed. |
| BR-CRF-138 : Provision of the reason for status change of a certificate is mandatory | RESOLVED | For each of the following operations:<br>• AMEND<br>• SUPPLEMENT<br>• RESTRICT<br>• SUSPEND<br>• RE-INSTATE<br>• WITHDRAW<br>• CANCELL BY MF<br><br>a reason for the status change is mandatory to be provided. |
| BR-CRF-139 : Conditions or limitations may be entered/edited only when issuing, supplementing, restricting or re-issuing a certificate | RESOLVED | Conditions or limitations may be entered/edited only when<br>• issuing<br>• supplementing<br>• restricting<br>• re-issuing<br><br>a certificate. |

| | | |
|---|---|---|
| BR-CRF-140 : Applicable risk classes per device group | RESOLVED | Depending of the regulation a device group may contain the following risk classes:<br><br>**Regulation** / **Device group risk classes**<br>MDR: I, IIa, IIb, III<br>IVDR: A, B, C, D |
| BR-CRF-141 : No issuing or re-issuing of a certificate allowed for a NB that has its designation ended | RESOLVED | EUDAMED will not allow to issue or re-issue new certificates by a Notified Body that is not designated (Status == Inactive). Existing/registered certificates will be possible to be updated. |
| BR-CRF-142 : Device group identification | RESOLVED | A device group is identified by its name and containing devices risk classes. |
| BR-CRF-144 : No data about the MF or AR or SPPP can be changed when performing a decision operation over an issued certificate | RESOLVED | In case of SUSPEND, RE-INSTATE, WITHDRAW or CANCELL BY MF (activities which refer to a decision taken with respect to a specific certificate<br>but do not touch the certificate as such), no data about the Manufacturer or Authorised representative (s) or System or Procedure Pack(s) Producer can be modified. |
| BR-CRF-145 : Number of decision documents to be uploaded | RESOLVED | In case of SUSPEND, RE-INSTATE, WITHDRAW or CANCELL BY MF (activities which refer to a decision taken with respect to a specific certificate<br>but do not touch the certificate as such), uploading of more than one of decision documents (PDF format) will be allowed. |
| BR-CRF-146 : Decision documents must not be available to public | RESOLVED | In case of SUSPEND, RE-INSTATE, WITHDRAW or CANCELL BY MF (activities which refer to a decision taken with respect to a specific certificate<br>but do not touch the certificate as such) all the uploaded decision documents must not be available to public. |
| BR-CRF-148 : Mandatory provision of conditions or limitations when amending a certificate | RESOLVED | When amending a certificate it is mandatory to provide conditions or limitations in the language(s) that has been added. |
| BR-CRF-149 : Possibility to update actors with their latest version when amending or re-issuing a certificate | RESOLVED | It will be possible to update to the last actor version for the following actors:<br>• Manufacturer (MF)<br>• Authorised Representative (AR)<br>• System or Procedure Pack Producer (SPPP)<br><br>when amending or re-issuing a certificate. |
| BR-CRF-153 : Re-issue certificate languages | RESOLVED | During the re-issue operation system will pre-populate and display all the languages from the preceding certificates. |
| BR-CRF-154 : Mandatory attributes for SS(C)P registration | RESOLVED | Notified Body must provide the following in order to register a SS(C)P:<br>• SS(C)P reference number<br>• SS(C)P revision number<br>• Date issued<br>• SS(C)P PDF master document<br>• Language of the SS(C)P PDF master document<br>• Answer of whether the SS(C)P master document is validated (Certificates of type quality only)<br>• At least one Basic UDI-DI |
| BR-CRF-156 : Upload an SS(C)P master document | RESOLVED | Notified Body must upload a single document in PDF format for a single instance of the SS(C)P. |
| BR-CRF-158 : An SS(C)P can reference more than one Basic UDI-DI | RESOLVED | An SS(C)P record is allowed to reference more than one Basic UDI-DI. As such, it is a one to many relationship between a single SS(C)P and many Basic UDI-DIs. |
| BR-CRF-159 : More than one SS(C)P can be registered | RESOLVED | It is possible to register more than one SS(C)P during certificate registration. |
| BR-CRF-160 : Language of an SS(C)P | RESOLVED | Notified Body must specify the language in which the SS(C)P master document is uploaded into EUDAMED. |
| BR-CRF-179 : Referencing Basic UDI-DI within SS(C)P | RESOLVED | A Basic UDI-DI cannot be attached to the same SS(C)P more than once. An SS(C)P record cannot have attached twice the same Basic UDI-DI. |
| BR-CRF-180 : Re-issued certificate versioning | RESOLVED | A re-issued certificate will have EUDAMED version 1. |

| | | |
|---|---|---|
| BR-CRF-181 : Notified Body can reference an existing SS(C)P record by checking the registry | RESOLVED | The system will allow Notified Body to re-use an existing SS(C)P record. When performing the search, the system will enforce the followings:<br>• SS(C)P record must reference Basic UDI-DI(s) registered by the Manufacturer that is referenced in this certificate registration;<br>• SS(C)P record is in REGISTERED state |
| BR-CRF-182 : Mandatory criteria when searching for an SS(C)P in the registry | RESOLVED | Following criteria must be provided when searching for an SS(C)P in EUDAMED registry:<br>• SS(C)P reference number<br>• SS(C)P revision number |
| BR-CRF-187 : Provision of the comments for status change of a certificate is mandatory | RESOLVED | For each of the following operations:<br>• AMEND<br>• SUPPLEMENT<br>• RESTRICT<br>• SUSPEND<br>• RE-INSTATE<br>• WITHDRAW<br>• CANCELL BY MF<br>a comment is mandatory to be provided in each of the languages selected or in that the preceding certificate was registered. |
| BR-CRF-190 : Certificate languages when supplementing or restricting a certificate | RESOLVED | No languages can be added or removed from a certificate that is being restricted or supplemented. |
| BR-CRF-191 : Restricting a certificate containing System or Procedure Pack | RESOLVED | When the certificate being restricted contains System or Procedure Pack(s) then the system will ensure that at least one System or Procedure Pack must remain within the scope of restricted certificate. |
| BR-CRF-192 : Special device type within certificates of type quality | RESOLVED | Special device type fields are mandatory to be provided at the registration of a certificate of type quality. Subsequently, the possibility to update special device type fields is allowed when:<br>• Supplementing<br>• Restricting<br>• Re-issuing<br>operations over a certificate. |
| BR-CRF-196 : Skip SS(C)P initial registration when issuing a certificate of type quality | RESOLVED | When a Notified Body is registering an issued certificate of the following type:<br>• (MDR / IVDR) EU Quality Management System certificate (Annex IX Chapter I)<br>• (MDR) EU Quality Assurance certificate (Annex XI Part A)<br>that references at least one Basic UDI-DI that requires the SS(C)P (inline with BR-CRF-118 and/or BR-CRF-119) and the Notified Body skips the provision of the SS(C)P then the system will issue a warning message. |
| BR-CRF-197 : SS(C)P scope | RESOLVED | The system will ensure that an SS(C)P record is linked to at least one Basic UDI-DI. |
| BR-CRF-200 : Actor update not allowed when supplementing or restricting a certificate | RESOLVED | When supplementing or restricting a certificate the system will display the actor (MF/AR/Producer) version from the preceding certificate. There will be no possibility to update actors version. |
| BR-CRF-201 : Update of device type | RESOLVED | Change of the device's type consisting of:<br>• Code that reflects the design and intended purpose of the device<br>• Horizontal codes<br>will be allowed only when supplementing/restricting or re-issuing a certificate. |
| BR-CRF-202 : Intended purpose of a device update | RESOLVED | Update of device's intended purpose description will be allowed only when supplementing/restricting or re-issuing a certificate. |
| BR-CRF-203 : SS(C)P registration within a certificate having its scope defined with Device group(s) | RESOLVED | When registering a certificate under MDR containing only Device group with risk class IIa or risk class IIb or IVDR containing only Device group with risk class C and when there is no Basic UDI-DI(s) provided then it will be mandatory for the Notified Body to provide a Basic UDI-DI(s) within the SS(C)P registration step. |
| BR-CRF-206 : Identification of a split operation when re-issuing quality certificate types | RESOLVED | When re-issuing a quality certificate type then EUDAMED will verify if the parent certificate has other re-issued certificates (children). When sibling certificates were identified the system will mark each child certificate as split. |
| BR-CRF-211 : System and/or Procedure pack group scope | RESOLVED | When System and/or Procedure pack group is applicable the system will ensure that at least one SPP group is provided during certificate registration. |
| BR-CRF-214 : Uniqueness of Basic UDI-DI within a certificate registration | RESOLVED | A Basic UDI-DI will be referenced once and only once within a single certificate. No duplicates will be allowed within the same certificate. |

| | | |
|---|---|---|
| BR-CRF-220 : Request for suspension /withdrawal only for active certificates | RESOLVED | Only active certificates (their expiry date is after the current date) having one of the following statuses:<br>• ISSUED<br>• AMENDED<br>• SUPPLEMENTED<br>• RESTRICTED<br>• RE-ISSUED<br>• RE-INSTATED<br>• SUSPENDED<br><br>can be requested for suspension/withdrawal by a Designating Authority. |
| BR-CRF-222 : Provision of comments when requesting withdrawal /suspension of certificates | RESOLVED | When confirming the request for suspension/withdrawal of certificate(s) the request date and comments are mandatory to be provided. |
| BR-CRF-223 : Multiplicity of authorised representative in the applications | RESOLVED | For the following application types for non-EU manufacturer **one and only one** authorised representative is required:<br>• REGULATION (EU) 2017/745.Annex IX Chapter II (Assessment of Technical Documentation)<br>• REGULATION (EU) 2017/745.Annex X (Type Examination)<br>• REGULATION (EU) 2017/745.Annex XI Part B (Product verification)<br>• REGULATION (EU) 2017/746.Annex IX Chapter II (Assessment of Technical Documentation)<br>• REGULATION (EU) 2017/746.Annex X (Type Examination)<br><br>For the following application types for a non-EU manufacturer **at least one** authorised representative is required:<br>• REGULATION (EU) 2017/745.Annex IX Chapter I (Quality Management System)<br>• REGULATION (EU) 2017/745.Annex XI Part A (Production Quality Assurance)<br>• REGULATION (EU) 2017/746.Annex IX Chapter I (Quality Management System)<br>• REGULATION (EU) 2017/746.Annex XI (Production Quality Assurance) |
| BR-CRF-225 : Maximum number of Basic UDI-DI in the scope of product applications for conformity | RESOLVED | The scope of the product certificates types<br>• REGULATION (EU) 2017/745.Annex IX Chapter II (Assessment of Technical Documentation)<br>• REGULATION (EU) 2017/745.Annex X (Type Examination)<br>• REGULATION (EU) 2017/745.Annex XI Part B (Product verification)<br>• REGULATION (EU) 2017/746.Annex IX Chapter II (Assessment of Technical Documentation)<br>• REGULATION (EU) 2017/746.Annex X (Type Examination)<br><br>can include **more than one** Basic UDI-DI. |
| BR-CRF-226 : SPP(s) only for MDR quality conformity assessment | RESOLVED | An application can include in its scope System or Procedure Pack(s) only if it is a MDR quality conformity assessment and references an SPP Producer. |
| BR-CRF-230 : Only one draft version linked to a certificate in state REGISTERED | RESOLVED | When a Notified Body performs one of the following operations:<br>• Suspend<br>• Withdraw<br>• Cancel by MF<br>• Re-instate<br>• Amend<br>• Restrict<br>• Supplement<br>• Re-issue<br><br>over a certificate in state registered that is linked to a draft version of it then the system will not allow any other operation over this certificate. |
| BR-CRF-233 : Registering a list of nominated experts | RESOLVED | When uploading a new nominated expert list document onto EUDAMED it will be mandatory to indicate the validity period by providing a **From** date. The **To** date is optional. System will ensure that provided **From** date is before than **To** date, if applicable. |
| BR-CRF-234 : Create a new SS(C)P version | RESOLVED | The system will not allow the creation of a new SS(C)P version from the SS(C)P management when the SS(C)P record is linked to a certificate in state DRAFT or the certificate linked is in state DRAFT (case of Issued, Amended, Supplemented, Restricted, Re-issued). |
| BR-CRF-235 : Cannot change the language of the master document when creating a new version of the SS (C)P | RESOLVED | The system will not allow to specify the language of the SS(C)P master document when creating a new version of that SS(C)P. |

| | | |
|---|---|---|
| BR-CRF-236 : Constraints for CA (XI) to certificate/refused certificate view page | RESOLVED | When viewing a certificate/refused certificate by a CA from Northern Ireland (XI) and that certificate contains<br><br>• [Mechanism for scrutiny] details<br>• Decision on refusal document<br><br>then the system will display the details only when at least one of the following conditions are met:<br><br>• NB place of business is Northern Ireland<br>• MF place of business is Northern Ireland<br>• AR place of business is Northern Ireland<br>• PR place of business is Northern Ireland<br>• Basic UDI-DI within the Mechanism for scrutiny or refused certificate has its Market distribution set to Northern Ireland |
| BR-CRF-237 : Constraints for CA (XI) to view refused/withdrawn applications | RESOLVED | When searching for refused/withdrawn applications for conformity assessment by a CA from Northern Ireland (XI) then the system will provide the results only when at least one of the following conditions are met:<br><br>• NB place of business is Northern Ireland<br>• MF place of business is Northern Ireland<br>• AR place of business is Northern Ireland<br>• Basic UDI-DI within the application has its Market distribution set to Northern Ireland |
| BR-CRF-240 : Optionality of 'Other' comment for status change reason | RESOLVED | It is mandatory to provide comments in all certificate languages if reason for status change is 'Other'. |
| BR-CRF-241 : Identification of Manufacturer/Producer when requesting certificates for suspension /withdrawal | RESOLVED | When requesting for suspension/withdrawal of certificates that are not yet registered in EUDAMED, the DA must identify the Manufacturer or System and/or Procedure Pack Producer. |
| BR-CRF-243 : Provision of a decision document when registering an application | RESOLVED | When registering a decision type: Refused application, a decision document may be uploaded. There will be no possibility to upload a decision document when registering a Withdrawn application decision type. |
| BR-CRF-244 : Device confirmation by a Notified Body | RESOLVED | A Notified Body must confirm the devices that are in state SUBMITTED and are being referenced in a product certificate registration. After the confirmation and successful product certificate registration the system will set the state to REGISTERED for all devices that were confirmed. |
| BR-CRF-245 : Find criteria for a certificate when merging two or more certificates | RESOLVED | When searching for a certificate to merge within a re-issue operation a Notified Body will provide:<br><br>• Preceding certificate number (mandatory)<br>• Preceding certificate revision number (optional) |
| BR-CRF-249 : Updating certificate languages when amending/re-issuing a certificate | RESOLVED | When amending or re-issuing a certificate the Notified Body can add new languages and/or remove languages from the preceding certificate during the registration process. |
| BR-CRF-251 : Change in certificate scope when restricting or reissuing a certificate | RESOLVED | When restricting or reissuing an MDR quality certificate that contains both device(s) and system(s) and /or procedure pack(s) sterilisation then the system will allow Notified Bodies to remove either:<br><br>1. System(s) and/or Procedure Pack(s) sterilisation from the scope or<br>2. all Device group(s) and/or device(s) from the scope.<br><br>(1) When removing System or Procedure Pack(s) sterilisation from certificate scope then the system will unlink the Producer from the restricted or reissued certificate;<br><br>(2) When removing all Device group(s) and/or Device(s) from certificate scope then the system will unlink the Manufacturer and its related Authorised Representative(s) (if present) from the restricted or reissued certificate. |
| BR-CRF-259 : Registering a MS summary report | RESOLVED | When registering a MS summary report the following fields must be provided:<br><br>• From date - indicates the starting period of the report;<br>• To date - indicates the end period of the report;<br>• Report in PDF file format.<br><br>The system will raise an error when "To date" cannot be before the "From date". The error message to be: 'The date "To" cannot be before the date "From"'<br><br>At the registration of a report, the system will automatically fill in the following data:<br><br>• Report ID - auto-generated in the format: NBMSR-CC-YYYY-X (CC-country code, YYYY- current year; X- sequential number);<br>• Member state - the country where the designating authority reside. |

| | | |
|---|---|---|
| BR-CRF-261 : View discarded requests for suspension/withdrawal of certificates | RESOLVED | The system will allow to view discarded requests for suspension/withdrawal of certificates only to DA owner, EC and CA actors. A DA can only view their own discarded requests for suspension/withdrawal of certificates. |
| BR-CRF-262 : Constraint on requesting for suspension/withdrawal of certificates | RESOLVED | A DA can register requests for suspension/withdrawal of certificates only for certificates issued by Notified Bodies that are under responsibility of that DA. |
| BR-CRF-266 : View discarded MS summary reports | RESOLVED | The system will allow EC/CA/DA actors to view or download MS summary reports in Registered or Discarded states. |

144 issues