EUDAMED Enumerations

Notified Bodies & Certificates

Production v 2.14.1
2024

Notified Bodies & Certificates - Enumerations

1 - Introduction

This "Enumerations" document contains the value lists for drop down elements and lists where a limited set of values can be selected.

2 - Purpose

This purpose of this document is to provide an overview of the possible values fields can contain to be valid information for EUDAMED.

3 - Scope

We opted to provide enumerations and their detailed descriptions by module. This document refers to Certificate module Enumerations only.

4 - Changelog

- No changes

5 - Enumerations

Summary	Status	Description
BR-CRF-003 : Applicable legislation for the certificate - ENUM_CRF_Regulation	RESOLVED	A certificate can be issued for one of the following regulations: **Label** / **Value** / **Notes** Regulation (EU) 2017/745 on Medical Devices / MDR / Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices / IVDR /

BR-CRF-004 : Certificate type - ENUM_CRF_CertificateType

RESOLVED

For MDR certificates (see) the certificate type can be:

Label	Value	Sort order
(MDR) EU Quality Management System certificate (Annex IX Chapter I)	MDR_QUALITY_MANAGEMENT_SYSTEM	1
(MDR) EU Technical Documentation certificate (Annex IX Chapter II)	MDR_TECHNICAL_DOCUMENTATION	2
(MDR) EU Type Examination certificate (Annex X)	MDR_TYPE_EXAMINATION	3
(MDR) EU Quality Assurance certificate (Annex XI Part A)	MDR_QUALITY_ASSURANCE	4
(MDR) EU Product verification certificate (Annex XI Part B)	MDR_PRODUCT_VERIFICATION	5

For IVDR certificates (see) the certificate type can be:

Label	Value	Sort order
(IVDR) EU Quality Management System certificate (Annex IX Chapter I)	IVDR_QUALITY_MANAGEMENT_SYSTEM	1
(IVDR) EU Technical Documentation certificate (Annex IX Chapter II)	IVDR_TECHNICAL_DOCUMENTATION	2
(IVDR) EU Type Examination certificate (Annex X)	IVDR_TYPE_EXAMINATION	3
(IVDR) EU Production Quality Assurance certificate (Annex XI)	IVDR_PRODUCTION_QUALITY_ASSURANCE	4

BR-CRF-027 : Risk Class - ENUM_CRF_RiskClass

RESOLVED

Regulation	Label	Value	Notes	Sort Order
IVDR	Class A	A		1
IVDR	Class B	B		2
IVDR	Class C	C		3
IVDR	Class D	D		4
MDR	Class I	I		5
MDR	Class IIa	IIa		6
MDR	Class IIb	IIb		7
MDR	Class III	III		8

BR-CRF-030 : List of certificate languages

RESOLVED

BR-EUD-005 : EU Languages - ENUM_MDR_LANGUAGE

BR-CRF-034 : Refused Certificate reason - ENUM_CRF_REFUSED_DecisionReason

RESOLVED

In case of refused certificate, the reason shall be one of the following:

Label	Value	Notes	Sort Order
Compliance: failure to close non-conformities	FAILURE_CLOSE_NON_CONFORMITIES		1
Compliance: Quality Management System failure	QUALITY_MGMT_SYSTEM_FAILURE	is applicable only in case of QMS/QA certificates	2
Compliance: product quality issues	PRODUCT_QUALITY_ISSUES		3
Compliance: Requirements of MDR/IVDR Regulations not met	MDR_IVDR_REGULATIONS_REQ_NOT_MET		4
Client: manufacturer has gone out of business	MNF_OUT_OF_BUSINESS		5
Client: fails to meet contractual obligations	FAILURE_CONTRACTUAL_OBLIGATIONS		6
Other	OTHER		7

Description always Mandatory

BR-CRF-037 : Certificate status - ENUM_CRF_CertificateStatus

RESOLVED

The certificate status can take the following values:

Label	Value	Notes
Issued	ISSUED	The first certificate that is issued (this status applies only when a certificate which a notified body has issued for a device/devices following an initial certification for a given manufacturer (SRN) is registered in EUDAMED)
Restricted	RESTRICTED	Reduce certificate scope and/or add conditions/limitations or impose restrictions on the validity of a certificate
Suspended	SUSPENDED	Suspend the validity of a certificate
Re-instated	REINSTATED	Re-instate a suspended certificate
Withdrawn	WITHDRAWN	Withdrawal of a certificate under specification of the reason(s)
Amended	AMENDED	Any updates to a certificate except scope, validity period and conditions/limitations/ restrictions
Supplemented	SUPPLEMENTED	Extend certificate scope and/or remove conditions/limitations/ restrictions
Re-issued	REISSUED	Re-issue an existing certificate before its expiration
Cancelled by MF	CANCELLED	Withdrawal of a certificate following the request from the manufacturer (e.g. because the device(s) are discontinued)

BR-CRF-041 : Device type - ENUM_CRF_DeviceType

RESOLVED

MDR Codes

Order	Code	Label	Notes

1	MDA0101	Active implantable devices for stimulation/inhibition/monitoring	
2	MDA0102	Active implantable devices delivering drugs or other substances	
3	MDA0103	Active implantable devices supporting or replacing organ functions	
4	MDA0104	Active implantable devices utilising radiation and other active implantable devices	
5	MDA0201	Active non-implantable imaging devices utilising ionizing radiation	
6	MDA0202	Active non-implantable imaging devices utilising non-ionizing radiation	
7	MDA0203	Active non-implantable devices for monitoring of vital physiological parameters	
8	MDA0204	Other active non-implantable devices for monitoring and/or diagnosis	
9	MDA0301	Active non-implantable devices utilising ionizing radiation	
10	MDA0302	Active non-implantable devices utilising non-ionizing radiation	
11	MDA0303	Active non-implantable devices utilising hyperthermia/hypothermia	
12	MDA0304	Active non-implantable devices for shock-wave therapy (lithotripsy)	
13	MDA0305	Active non-implantable devices for stimulation or inhibition	
14	MDA0306	Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	
15	MDA0307	Active non-implantable respiratory devices	
16	MDA0308	Active non-implantable devices for wound and skin care	
17	MDA0309	Active non-implantable ophthalmologic devices	
18	MDA0310	Active non-implantable devices for ear, nose and throat	
19	MDA0311	Active non-implantable dental devices	
20	MDA0312	Other active non-implantable surgical devices	
21	MDA0313	Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	
22	MDA0314	Active non-implantable devices for processing and preservation of human cells, tissues or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	

23	MD A0315	Software	
24	MD A0316	Medical gas supply systems and parts thereof	
25	MD A0317	Active non-implantable devices for cleaning, disinfection and sterilisation	
26	MD A0318	Other active non-implantable devices	
27	MD N1101	Non-active cardiovascular, vascular and neurovascular implants	
28	MD N1102	Non-active osteo- and orthopaedic implants	
29	MD N1103	Non-active dental implants and dental materials	
30	MD N1104	Non-active soft tissue and other implants	
31	MD N1201	Non-active non-implantable devices for anaesthesia, emergency and intensive care	
32	MD N1202	Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	
33	MD N1203	Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	
34	MD N1204	Non-active non-implantable devices for wound and skin care	
35	MD N1205	Non-active non-implantable orthopaedic and rehabilitation devices	
36	MD N1206	Non-active non-implantable ophthalmologic devices	
37	MD N1207	Non-active non-implantable diagnostic devices	
38	MD N1208	Non-active non-implantable instruments	
39	MD N1209	Non-active non-implantable dental materials	
40	MD N1210	Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases	
41	MD N1211	Non-active non-implantable devices for disinfecting, cleaning and rinsing	
42	MD N1212	Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	
43	MD N1213	Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	
44	MD N1214	General non-active non-implantable devices used in health care and other non-active non-implantable devices	

MDR HORIZONTAL CODES

Order	Code	Label	Notes
1	MDS1001	Devices incorporating medicinal substances	
2	MDS1002	Devices manufactured utilising tissues or cells of human origin, or their derivatives	
3	MDS1003	Devices manufactured utilising tissues or cells of animal origin, or their derivatives	
4	MDS1004	Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)	
5	MDS1005	Devices in sterile condition	
6	MDS1006	Reusable surgical instruments	
7	MDS1007	Devices incorporating or consisting of nanomaterial	
8	MDS1008	Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body	
9	MDS1009	Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices	
10	MDS1010	Devices with a measuring function	
11	MDS1011	Devices in systems or procedure packs	
12	MDS1012	Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745	
13	MDS1013	Class III custom-made implantable devices	
14	MDS1014	Devices incorporating as an integral part an in vitro diagnostic device	
15	MDT2001	Devices manufactured using metal processing	

16	MDT2002	Devices manufactured using plastic processing	
17	MDT2003	Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)	
18	MDT2004	Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)	
19	MDT2005	Devices manufactured using biotechnology	
20	MDT2006	Devices manufactured using chemical processing	
21	MDT2007	Devices which require knowledge regarding the production of pharmaceuticals	
22	MDT2008	Devices manufactured in clean rooms and associated controlled environments	
23	MDT2009	Devices manufactured using processing of materials of human, animal, or microbial origin	
24	MDT2010	Devices manufactured using electronic components including communication devices	
25	MDT2011	Devices which require packaging, including labelling	
26	MDT2012	Devices which require installation, refurbishment	
27	MDT2013	Devices which have undergone reprocessing	

IVDR Codes

Order	Code	Label	Notes
1	IVR0101	Devices intended to determine markers of the ABO system [A (ABO1), B (ABO2), AB (ABO3)]	
2	IVR0102	Devices intended to determine markers of the Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)]	

3	IVR0103	Devices intended to determine markers of the Kell system [Kel1 (K)]	
4	IVR0104	Devices intended to determine markers of the Kidd system [JK1 (Jka), JK2 (Jkb)]	
5	IVR0105	Devices intended to determine markers of the Duffy system [FY1 (Fya), FY2 (Fyb)]	
6	IVR0106	Other devices intended to be used for blood grouping	
7	IVR0201	Devices intended to be used for tissue typing (HLA A, B, DR) to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration	
8	IVR0202	Other devices intended to be used for tissue typing	
9	IVR0301	Devices intended to be used in screening, diagnosis, staging or monitoring of cancer	
10	IVR0302	Other devices intended to be used for markers of cancer and non-malignant tumours	
11	IVR0401	Devices intended to be used in screening/confirmation of congenital/inherited disorders	
12	IVR0402	Devices intended to be used to predict genetic disease/disorder risk and prognosis	
13	IVR0403	Other devices intended to be used for human genetic testing	
14	IVR0501	Devices intended to be used for pre-natal screening of women in order to determine their immune status towards transmissible agents	

15	IVR0502	Devices intended to be used to detect the presence of, or exposure to transmissible agents in blood, blood components, cells, tissues or organs, or in any of their derivatives, to assess their suitability for transfusion, transplantation or cell administration	
16	IVR0503	Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents	
17	IVR0504	Devices intended to be used to determine the infectious load, to determine infective disease status or immune status and devices used for infectious disease staging	
18	IVR0505	Devices intended to be used to grow/isolate/identify and handle infectious agents	
19	IVR0506	Other devices intended to be used to determine markers of infections/immune status	
20	IVR0601	Devices intended to be used for screening/confirmation of specific disorders/impairments	
21	IVR0602	Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease	
22	IVR0603	Devices intended to be used for screening, confirmation/determination, or monitoring of allergies and intolerances	
23	IVR0604	Other devices intended to be used for a specific disease	
24	IVR0605	Devices intended to be used for monitoring of levels of medicinal products, substances or biological components	
25	IVR0606	Devices intended to be used for non-infectious disease staging	
26	IVR0607	Devices intended to be used for detection of pregnancy or fertility testing	

27	IVR0608	Devices intended to be used for screening, determination or monitoring of physiological markers	
28	IVR0609	Other devices intended to be used to define or monitor physiological status and therapeutic measures	
29	IVR0701	Devices which are controls without a quantitative assigned value	
30	IVR0702	Devices which are controls without a qualitative assigned value	
31	IVR0801	Devices referred to in point 2.5 (rule 5), under a), of Annex VIII to Regulation (EU) 2017/746	
32	IVR0802	Instruments intended specifically to be used for in vitro diagnostic procedures referred to in point 2.5 (rule 5), under b), of Annex VIII to Regulation (EU) 2017/746	
33	IVR0803	Specimen receptacles referred to in point 2.5 (rule 5), under c), of Annex VIII to Regulation (EU) 2017/746	

IVDR Horizontal Codes

Order	Code	Label	Notes
1	IVS1001	Devices intended to be used for near-patient testing	
2	IVS1002	Devices intended to be used for self-testing	
3	IVS1003	Devices intended to be used as companion diagnostics	
4	IVS1004	Devices manufactured utilising tissues or cells of human origin, or their derivatives	
5	IVS1005	Devices in sterile condition	
6	IVS1006	Calibrators (point 1.5 of Annex VIII to Regulation (EU) 2017/746)	

7	IV S1 007	Control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes (point 1.6 of Annex VIII to Regulation (EU) 2017 /746)	
8	IV S1 008	Instruments, equipment, systems or apparatus	
9	IV S1 009	Software that are devices in themselves including software apps, software for data analysis, and for defining or monitoring therapeutic measures	
10	IV S1 010	Devices incorporating software/utilising software/controlled by software	
11	IVT 20 01	In vitro diagnostic devices manufactured using metal processing	
12	IVT 20 02	In vitro diagnostic devices manufactured using plastic processing	
13	IVT 20 03	In vitro diagnostic devices manufactured using non-metal mineral processing (e.g. glass, ceramics)	
14	IVT 20 04	In vitro diagnostic devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)	
15	IVT 20 05	In vitro diagnostic devices manufactured using biotechnology	
16	IVT 20 06	In vitro diagnostic devices manufactured using chemical processing	
17	IVT 20 07	In vitro diagnostic devices which require knowledge regarding the production of pharmaceuticals	
18	IVT 20 08	In vitro diagnostic devices manufactured in clean rooms and associated controlled environments	
19	IVT 20 09	In vitro diagnostic devices manufactured using processing of materials of human, animal or microbial origin	
20	IVT 20 10	In vitro diagnostic devices manufactured using electronic components including communication devices	
21	IVT 20 11	In vitro diagnostic devices which require packaging, including labelling	
22	IV P3 001	In vitro diagnostic devices which require knowledge regarding agglutination tests	
23	IV P3 002	In vitro diagnostic devices which require knowledge regarding biochemistry	
24	IV P3 003	In vitro diagnostic devices which require knowledge regarding chromatography	
25	IV P3 004	In vitro diagnostic devices which require knowledge regarding chromosomal analysis	
26	IV P3 005	In vitro diagnostic devices which require knowledge regarding coagulometry	
27	IV P3 006	In vitro diagnostic devices which require knowledge regarding flow cytometry	
28	IV P3 007	In vitro diagnostic devices which require knowledge regarding immunoassays	

29	IV P3 008	In vitro diagnostic devices which require knowledge regarding lysis based testing	
30	IV P3 009	In vitro diagnostic devices which require knowledge regarding measurement of radioactivity	
31	IV P3 010	In vitro diagnostic devices which require knowledge regarding microscopy	
32	IV P3 011	In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)	
33	IV P3 012	In vitro diagnostic devices which require knowledge regarding physical chemistry including electrochemistry	
34	IV P3 013	In vitro diagnostic devices which require knowledge regarding spectroscopy	
35	IV P3 014	In vitro diagnostic devices which require knowledge regarding tests of cell function	
36	IV D4 001	In vitro diagnostic devices which require knowledge regarding bacteriology	
37	IV D4 002	In vitro diagnostic devices which require knowledge regarding clinical chemistry /biochemistry	
38	IV D4 003	In vitro diagnostic devices which require knowledge regarding detection of transmissible agents (without organisms or viruses)	
39	IV D4 004	In vitro diagnostic devices which require knowledge regarding genetics	
40	IV D4 005	In vitro diagnostic devices which require knowledge regarding haematology /haemostasis, including coagulation disorders	
41	IV D4 006	In vitro diagnostic devices which require knowledge regarding histocompatibility and immunogenetics	
42	IV D4 007	In vitro diagnostic devices which require knowledge regarding immunohistochemistry /histology	
43	IV D4 008	In vitro diagnostic devices which require knowledge regarding immunology	
44	IV D4 009	In vitro diagnostic devices which require knowledge regarding molecular biology /diagnostics	
45	IV D4 010	In vitro diagnostic devices which require knowledge regarding mycology	
46	IV D4 011	In vitro diagnostic devices which require knowledge regarding parasitology	
47	IV D4 012	In vitro diagnostic devices which require knowledge regarding virology	

BR-CRF-086 : Amended Certificate status change reason - ENUM_CRF_AMENDED_StatusChangeReason

RESOLVED

Label	Value	Notes	Sort Order
Editorial change of manufacturer/authorized representative	AMENDED_MNF_AR_CHANGE		1
Change of manufacturer's data	AMENDED_MNF_DATA_CHANGE		2
Change of Authorised representative's data	AMENDED_AR_DATA_CHANGE		3
Change of Authorised representative (SRN)	AMENDED_AR_SRN_CHANGE		4
Other	AMENDED_OTHER		5

BR-CRF-087 : Refusal application reason - ENUM_CRF_APPL_DecisionReason

RESOLVED

Label	Value	Notes	Sort Order
Application not complete	APPLICATION_NOT_COMPLETE		1
Wrong qualification of product/classification of the device	WRONG_QUALIFICATION_DEVICE		2
Wrong conformity assessment procedure chosen	WRONG_CONFORMITY_ASSESSMENT_PROCEDURE		3
Outside the scope of the notified body's designation	OUT_OF_SCOPE_NB		4
Insufficient notified body resources	NOT_SUFFICIENT_RESOURCES_NB		5
Other	OTHER		6

BR-CRF-088 : Cancelled by MF Certificate status change reason - ENUM_CRF_CANCELLEDBYMF_StatusChangeReason

RESOLVED

Label	Value	Notes	Sort Order
Other	CANCELLED_OTHER		1

BR-CRF-091 : Designating authority reason for suspension/withdrawal of certificate(s) - ENUM_CRF_DARequestReason

RESOLVED

Label	Value	Sort Order
Request for suspension	CertRfS	1
Request for withdrawal	CertRfW	2

BR-CRF-091 : System or Procedure pack applicable - ENUM_CRF_CertificateSPPType

RESOLVED

Label	Value	Notes	Sort Order
Includes only systems and/or procedure packs	ONLY_SPP		1
Includes both devices and systems and/or procedure packs	BOTH_DEVICE_AND_SPP		2

BR-CRF-092 : Decision type - ENUM_CRF_Decision

RESOLVED

Label	Value	Notes	Sort Order
Withdrawn application (by MF)	WITHDRAWN_APPLICATION		1
Application refusal (by NB)	APPLICATION_REFUSAL		2
Refused certificate (by NB)	REFUSED_CERTIFICATE		3

BR-CRF-093 : Designation notification status - ENUM_CRF_DesignationNotificationStatus

RESOLVED

Label	Value	Notes	Sort Order
EXPIRED	EXPIRED		1
SUSPENDED	SUSPENDED		2
WITHDRAWN	WITHDRAWN		3

BR-CRF-094 : Class I device characteristics - ENUM_CRF_DeviceCharacteristics

RESOLVED

Label	Value	Notes	Sort Order
Re-usable surgical instrument	REUSABLE		1
With a measuring function	MEASURING_FUNCTION		2
Placed on the market in sterile condition	STERILE		3

BR-CRF-095 : Reinstated Certificate status change reason - ENUM_CRF_REINSTATED_StatusChangeReason

RESOLVED

Label	Value	Notes	Sort Order
Certificate re-instated as issue now resolved	REINSTATED_ISSUE_RESOLVED		1
Other	REINSTATED_OTHER		2

BR-CRF-096 : Restricted Certificate status change reason - ENUM_CRF_RESTRICTED_StatusChangeReason

RESOLVED

Label	Value	Notes	Sort Order
Compliance: substantial changes implemented before approval	RESTRICTED_CHANGES_BEFORE_APPROVAL		1
Compliance: failure to close non-conformities	RESTRICTED_FAILURE_NON_CONFORMITIES		2
Compliance: Quality Management System failure	RESTRICTED_FAILURE_QUALITY_MANAGEMENT		3
Compliance: product quality issues	RESTRICTED_PRODUCT_QUALITY_ISSUES		4
Compliance: Requirements of the MDR/IVDR Regulations not met	RESTRICTED_MDR_IVDR_REQ_NOT_MET		5
Product: obsolete – no longer placed on the market	RESTRICTED_NOT_ON_MARKET		6
Product: has been reclassified	RESTRICTED_PRODUCT_RECLASSIFIED		7
NB reduces certificate scope	RESTRICTED_REDUCE_SCOPE		8
Other	RESTRICTED_OTHER		9

BR-CRF-099 : Special Device Type - ENUM_CRF_SpecialDeviceType

RESOLVED

MDR

Label	Value
Devices manufactured utilising tissues or cells of animal origin, or their derivatives	Yes /No
Devices manufactured utilising tissues or cells of human origin, or their derivatives	Yes /No
Devices in sterile condition	Yes /No
Devices incorporating as an integral part an in vitro diagnostic device (valid only for MDR certs)	Yes /No
Devices without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017 /745	Yes /No

IVDR

Label	Value
Devices manufactured utilising tissues or cells of animal origin, or their derivatives	Yes/No
Devices manufactured utilising tissues or cells of human origin, or their derivatives	Yes/No
Devices in sterile condition	Yes/No

BR-CRF-100 : Supplemented Certificate status change reason - ENUM_CRF_SUPPLEMENTED_StatusChangeReason

RESOLVED

Label	Value	Notes	Sort Order
Product: add a device(s)/group of device (s)	SUPPLEMENTED_DEVICE_GROUP		1
Product: change to the approved type /device	SUPPLEMENTED_CHANGE_APPROVED		2
Other	SUPPLEMENTED_OTHER		3

BR-CRF-101 : Suspended Certificate status change reason - ENUM_CRF_SUSPENDED_StatusChangeReason

RESOLVED

Label	Value	Notes	Sort Order
Compliance: substantial changes implemented before approval	SUSPENDED_CHANGES_BEFORE_APPROVAL		1
Compliance: failure to close non-conformities	SUSPENDED_FAILURE_NON_CONFORMITIES		2
Compliance: Quality Management System failure	SUSPENDED_FAILURE_QUALITY_MANAGEMENT		3
Compliance: product quality issues	SUSPENDED_PRODUCT_QUALITY_ISSUES		4
Compliance: Requirements of the MDR /IVDR Regulations not met	SUSPENDED_MDR_IVDR_REQ_NOT_MET		5
Client: fails to meet contractual obligations	SUSPENDED_FAILURE_CONTRACTUAL_OBLIGATIONS		6
Other	SUSPENDED_OTHER		7

BR-CRF-102 : Withdrawn Certificate status change reason - ENUM_CRF_WITHDRAWN_StatusChangeReason

RESOLVED

Label	Value	Notes	Sort Order
Compliance: substantial changes implemented before approval	WITHDRAWN_CHANGES_BEFORE_APPROVAL		1
Compliance: failure to close non-conformities	WITHDRAWN_FAILURE_NON_CONFORMITIES		2
Compliance: Quality Management System failure	WITHDRAWN_FAILURE_QUALITY_MANAGEMENT		3
Compliance: product quality issues	WITHDRAWN_PRODUCT_QUALITY_ISSUES		4
Compliance: Requirements of the MDR /IVDR Regulations not met	WITHDRAWN_MDR_IVDR_REQ_NOT_MET		5
Product: obsolete – no longer placed on the market	WITHDRAWN_NOT_ON_MARKET		6
Product: has been reclassified	WITHDRAWN_PRODUCT_CLASSIFIED		7
Client: is no longer the legal manufacturer	WITHDRAWN_NOT_LEGAL_MANUFACTURER		8
Client: has transferred to another NB	WITHDRAWN_TRANSFERRED_TO_OTHER_NB		9
Client: fails to meet contractual obligations	WITHDRAWN_FAILURE_CONTRACTUAL_OBLIGATIONS		10
Other	WITHDRAWN_OTHER		11

BR-CRF-103 : Certificate states - ENUM_CRF_WorkflowState

RESOLVED

Label	Value	Notes
DRAFT	DRAFT	When saving a certificate version in EUDAMED, its state is Draft until it is submitted to EUDAMED for 'official registration'. A certificate version in the Draft state can be physically deleted and updated and it is only visible in the restricted EUDAMED site to the NB actor that saved it.
REGISTERED	REGISTERED	When a certificate version is submitted to EUDAMED for 'official registration' its state becomes Registered. A certificate version in this state cannot be physically deleted or updated. It can only be set to 'DISCARDED' or associated to a new certificate version.
DISCARDED	DISCARDED	A certificate version of can be set the 'DISCARDED' state by the NB in order to perform corrections (re-submit a new corrected certificate version). This can be done only when the certificate version is 'REGISTERED'. The last version of the certificate in state 'REGISTERED' will become in this case the active version of the certificate.

BR-CRF-106 : Application states - ENUM_Applicatiion_WorkflowState

RESOLVED

Label	Value	Notes
DRAFT	DRAFT	When saving an application in EUDAMED, its state is Draft until it is submitted to EUDAMED for 'official registration'. An application in the Draft state can be physically deleted and updated and it is only visible in the restricted EUDAMED site to the NB actor that saved it.
REGISTERED	REGISTERED	When an application is submitted to EUDAMED for 'official registration' its state becomes Registered. An application in this state cannot be physically deleted or updated. It can only be set to 'DISCARDED'.
DISCARDED	DISCARDED	An application can be set the 'DISCARDED' state by the NB in order to perform corrections (re-submit a new corrected application). This can be done only when the certificate version is 'REGISTERED'.

BR-CRF-112 : Device identification type - ENUM_CRF_DeviceIdentificationTypes

RESOLVED

Label	Value	Notes	Sort Order
Name	DEVICE_NAME		1
Reference/Catalogue number	DEVICE_REFERENCE_CATALOGUE		2
Basic UDI-DI	BASIC_UDI_DI		3

BR-CRF-140 : Application refusal /wthdrawal decision type - ENUM_CRF_RefuseWithdrawDecisionType

RESOLVED

Label	Value	Notes	Sort Order
Withdrawn application (by MF)	WITHDRAWN_APPLICATION		1
Application refusal (by NB)	APPLICATION_REFUSAL		2

BR-CRF-189 : Systems and Procedure Pack sterilisation method - ENUM_CRF_SPPSterilisationMethod

RESOLVED

Possible values for the selection of the sterilisation method when registering a System and Procedure Pack within a QMS certificate:

Label	Value	Order
Aseptic processing	ASEPTIC_PROCESSING	1
Ethylene oxide gas sterilisation (EOG)	EOG	2
Low temperature steam and formaldehyde sterilisation	LOW_TEMPERATURE	3
Moist heat sterilisation	MOIST_HEAT	4
Radiation sterilisation (gamma, x-ray, electron beam)	RADIATION	5
Others	OTHERS	6

BR-CRF-208 : SS(C)P uploaded from - ENUM_CRF_SSCPUploadedFrom

RESOLVED

Possible values for the upload of an SS(C)P

Label	Value
Certificate registration	SSCPUpload_Cert
SS(C)P Management	SSCPUpload_Mgmt

BR-CRF-260 : Request for suspension/withdrawal of certificates states - ENUM_CRF_DARequestState

RESOLVED

Label	Value	Notes	Order
Registered	REGISTERED	Request for suspension/withdrawal is visible to DA, EC and CA	1
Discarded	DISCARDED	Visible only to EC, CA and the DA owner.	2

28 issues


European
Commission