CRF
Refusal of a certificate
MDR Eudamed

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Document Control Information

Settings	Value
Project Title:	MDR Eudamed
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Scope

This document shows the different business rules related to all certificate fields when registering a refused certificate.
It has to be noted that rules and fields presented in this document relate to the Eudamed system, not to the paper certificate.

Legend

Code	Description
E	To be entered – Mandatory to enter new data
P	Possible to be entered – Optional
A	Auto-populated by EUDAMED

Format

Column	Description
Field	Field label and Data Dictionary field reference
Refused Certificate	Data entry rules for the respective data fields
Explanations and Rules	Details about the possible operations

FIELD	REFUSED CERTIFICATE	EXPLANATIONS AND RULESs
Notified Body ID FLD-CRF-315	A	Notified Body ID number (NB Identification number from Nando), automatically identified from user acting on behalf of NB.
Application reference number FLD-CRF-314	E	Unique identification number given by the notified body to the application (unique for a given notified body). Notified Body ID number and Application reference number together must be overall unique (FLD-CRF-315 + FLD-CRF-314 must be unique)
Certificate refusal date FLD-CRF-302	E	This date refers to the date when the decision on the refusal is taken and it is consistent with the date of the decision document which can optionally be uploaded in EUDAMED.
Manufacturer FLD-CRF-316 FLD-CRF-318	E *	The manufacturer will be picked up by the notified body among those ones registered in the actor module. The refused certificate will not be impacted by subsequent changes of the manufacturer (or other relevant actors) as registered in the Actor module. The refused certificate will keep the valid version of the manufacturer at the time the refused certificate was entered. (*: always applicable except for Quality procedure only for System/Procedure pack)
Systems and procedure packs producer (SPPP) FLD-CRF-319	E *	Same conditions as for manufacturers apply with reference to a refused certificate for systems and/or procedure packs. Should a refused certificate be related to both devices and systems/procedure packs, two SRNs will be reported. (*: only applicable for QMS/QA certificates with System/Procedure pack)

Authorised Rep FLD-CRF-317 FLD-CRF-320	**E ***	In case of non-EU manufacturer, the Authorised Representative(s) (could be more than 1) will be picked up by the notified body among those ones associated to the concerned manufacturer. (*: only applicable in case application was done by a non-EU manufacturer)
Conformity assessment procedure FLD-CRF-306	**E**	The conformity assessment procedure the manufacturer applied for will be entered by the notified body selecting from a drop-down menu.
Identification of devices/groups of devices in the scope and/or System/Procedure pack for QMS/QA conformity assessment procedure or (Basic UDI-DI), Name, Model and Type for Product conformity assessment procedure FLD-CRF-215, FLD-CRF-217, FLD-CRF-218, (device), FLD-CRF-221 (device group), FLD-CRF-213 (system/procedure pack), FLD-CRF-228 (custom-made device)	**E/A ***	The notified body will describe the devices/groups of devices/Systems/Procedure packs in the scope. The description of the scope will be performed by entering the same fields that are requested for issued certificates (see Data for Certificates matrix document), depending on whether dealing with product or quality system certificates. However, Basic UDI-DI is required only for product conformity assessment procedure requiring their assignment before a request for certificate (MDR Art 29(3), IVDR Art 26(2)), otherwise optional. (*: If Basic UDI-DI is provided and is already registered in EUDAMED, Name and Model will be automatically coming from the Basic UDI-DI data in EUDAMED)
Risk classification FLD-CRF-207 FLD-CRF-219 FLD-CRF-222	**E/A**	The risk class of the device(s) will be selected by the notified body when entering the refused certificate. Multiple choices are allowed. In case Basic UDI-DI that is registered in EUDAMED is used for the identification of the device, risk classification of the device will be automatically set from Basic UDI-DI data in EUDAMED.

Intended purpose FLD-CRF-210	E *	In case of Product conformity assessment procedures, the intended purpose will be requested for each device (*: not applicable in case of QMS/QA certificates).
Decision on refusal document FLD-CRF-313	P	The Notified body will issue a decision related to the refusal of the certificate and such a decision could be uploaded in EUDAMED.
Reason for refusal FLD-CRF-311 ENUM_CRF_REFUSED_DecisionReason	E	The reason for refusal has to be entered in EUDAMED. The following drop-down menu will be shown by the system: • Compliance: failure to close non-conformities • Compliance: Quality Management System failure • Compliance: product quality issues • Compliance: Requirements of MDR/IVDR Regulations not met • Client: manufacturer has gone out of business • Client: fails to meet contractual obligations • Other The reason "Compliance: Quality Management System failure" is applicable only in case of QMS/QA certificates.
Reason for refusal comment FLD-CRF-304	E	This field is a mandatory free text to complement Reason for refusal.
Date of submission of manufacturer's application	E	The date when the manufacturer's application for certification was submitted has to be provided in EUDAMED.

FLD-CRF-303		
Language FLD-CRF-328	**E**	The notified body will be requested to select the language in which the decision on refusal is issued by a drop-down menu. Multiple choices are allowed.