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Draft Functional specifications for the European Database on Medical Devices (Eudamed) - First release (High(1)) to be audited

First draft consolidated version of functional specifications for Eudamed (version 4.1)

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1. MDR Eudamed Justification

Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices were published in the OJ on 5 April 2017, entered into force on 25 May 2017 and shall apply from 26 May 2020 and from 26 May 2022 respectively. They will repeal Council Directives 90/385/EEC on active implantable medical devices, 93/42/EEC on medical devices and 98/79/EC on in vitro diagnostic medical devices.

Article 33 of Regulation (EU) 2017/745 and Article 30 of Regulation (EU) 2017/746 are the main articles requiring the setting up, maintenance and management of the future Eudamed by the Commission, after consulting the Medical Device Coordination Group (MDCG) made of one representative per Member State and chaired by the Commission. These Articles are furthermore associated to almost 50 other articles in each Regulation which means that Eudamed is a keystone for the implementation of the new Regulations, enabling many things, among which devices' traceability and better health protection thanks to an effective proactive market surveillance.

2. Purpose & Audience

Article 34 of Regulation (EU) 2017/745 obliges the Commission to draw up the functional specifications for Eudamed in collaboration with the MDCG and to draw up a plan for the implementation of those specifications by 26 May 2018, which shall seek to ensure that Eudamed is fully functional, and considered as such by an independent audit report, by March 2020.

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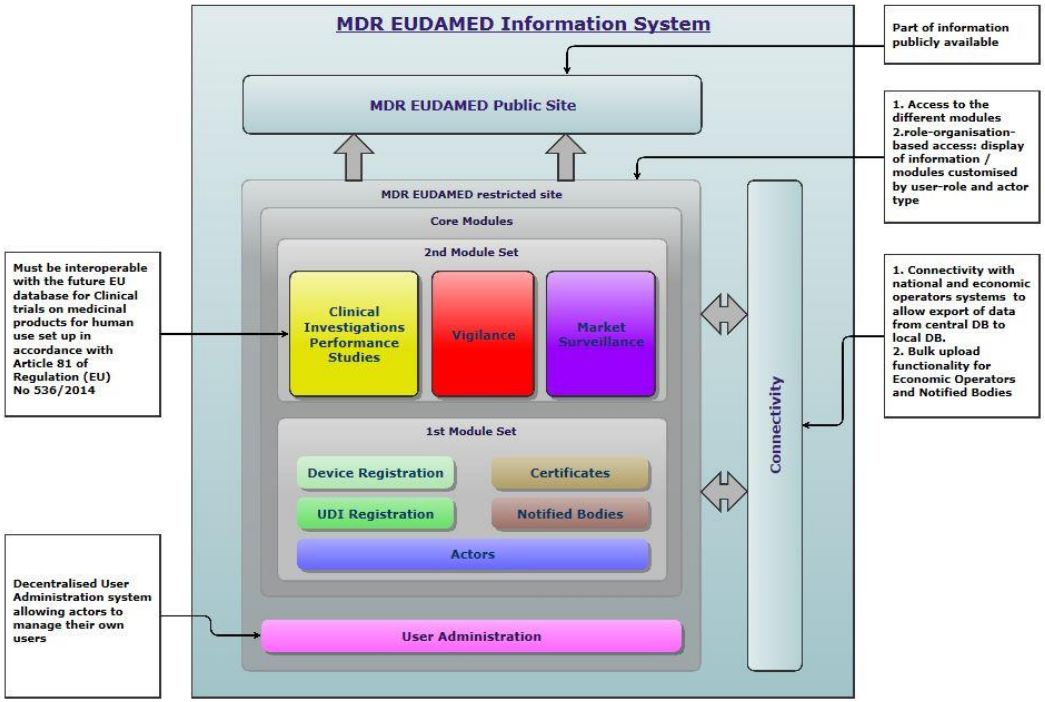
3. Project Overview



4. Project Deliverables

The main expected outcome is that thanks to MDR Eudamed the implementation of the medical devices regulations will be de facto possible and successful, but also that the stakeholders with legal obligations will be able to comply with the regulations.

ID	Deliverable Name	Deliverable Description
1	Mock-ups and prototypes	Visual representation of the future design shall be produced in order to support use cases modelling. Mock-ups and prototypes of the different modules shall be produced to support use cases modelling and get early feedback from stakeholders.
2	Functional specifications for the Audit and their implementation plan in collaboration with the MDCG	The Commission shall, in collaboration with the MDCG, draw up the functional specifications for Eudamed. The Commission shall draw up a plan for the implementation of these specifications at the latest 12 months after entry into force of the regulation.
3	MDR EUDAMED information system/database (1 database with 2 websites: Webgate and Europa)	Central system on medical devices and in vitro diagnostic medical devices containing the modules stated in the section 3 Project Overview. The system consists of: - a restricted website (Webgate) for database content management with access to all data an authorised user has the right to access. It allows all actors to fulfil their legal obligations and to search and view data they may access; - a public website on Europa for anonymous users to search and view data publically available. The two websites will be available from the Internet. Besides the two official websites, an Acceptance website for the restricted website will be as well available from the Internet for testing and learning purposes (only for dummy data).
4	User guide and technical documentation	A user guide in all official languages shall be provided for the information system. Technical documentation shall be provided where needed (e.g. for bulk upload functionality and machine to machine communication).
5	Training and training material and online training facilities (e-Learning)	Training material shall be provided for the main stakeholders. Training for the Information System shall be provided to and in collaboration by the Member States (train the trainers approach).
6	Technical Support	An application support team and framework shall be set up for providing technical support to the users of the system after go-live.

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5. Document Structure

- Point 6 contains the abbreviations used within this document
- Point 7 covers the legal requirements taken from both applicable regulations as stated in the MDR Eudamed justification
- Point 8 covers the functional specification derived from the legal requirements for the MDR Eudamed Information system

  The functional specifications are divided between the restricted website and the public website, each contain their functional specifications grouped by the modules who make up the MDR Eudamed system.

  An overview of these modules can be found under the project overview under point 3

- Point 9 covers the Non-Functional specifications

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6. Legend

Abbreviation	Description
ACT	Actor Module
AR	Authorised Representative
CA	Competent Authority
CCA	Coordinating Competent Authority
CECP	Clinical Evaluation Consultation Procedure
CIP	Clinical investigation plan (MD)
CIPS	Clinical Investigation / Performance Studies Module
CMS	Coordinating Member State
CRF	Certificates / Notified Body Module
DA	Designating Authority
DTX	Data Exchange Module
EC	European Commission
EU MF	European Manufacturer
EUD	LR or FS on the MDR Eudamed project level, covering all modules
FS	Functional Specification
FSCA	Field Safety Corrective Action
FSN	Field Safety Notice
IAM	Related to data protection LR or FS on the MDR Project Level, covering all modules
LR	Legal Requirement
MS	Member State
MSC	Member State concerned Note: For the purpose of this document the term 'Member State' is a synonymous of 'Member State concerned'.
MSU	Market Surveillance Module
NB	Notified Body
NFS	Non – Functional Specification
Non-EU MF	Non-European Manufacturer
PMCF	Post market clinical follow up (MD)

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PMPF	Post market performance follow up (IVD)
PSP	Performance study plan (IVD)
PSR	Periodic Summary Report on serious incidents
PSUR	Periodic Safety Update Report
SAE	Serious adverse event
SIR	Serious Incident Report
SIN	Single Identification Number for a CIPS
SPPP	System/Procedure pack Producer
SRN	Single Registration Number for an economic operator
SS(C)P	Summary of Safety and (Clinical) Performance
TR	Trend Report
UDID	UDI / Device Module
VGL	Vigilance Module
Legal Priority	The "Legal Priority" is an indication of the importance of the specific functional specification derived from the legal requirement. Possible values are: • "Required" meaning directly required from the MDRs; • "Necessary" meaning not directly established in the MDRs but indirectly related to a LR and necessary to make the system workable and useful, to improve data quality or agreed in the WGs; • "Nice to have" meaning not strictly required from LR and not necessary for the workability of Eudamed. Usually an extra feature that could be considered as an advanced one that could be implemented at a second stage (in a further release).
Timing Priority	The "Timing Priority" gives an indication in what order the specific functional specification will be provided. Possible values are: High (1): Functional specification part of the first release in March 2020 Medium(2): Functional specification part of a next release in 2020 Low(3): Functional specification for later release (To be planned)

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7. Legal requirements – LR

7.1. Actor - ACT

Stakeholder	Stakeholder Task	Eudamed Requirement (Eudamed shall allow/enable)	Module	Requirement ID No	Legal Basis (MDR)	Legal Basis (IVDR)
Manufacturer	Submit actor data for registration and for accessing Eudamed	Enable manufacturer to submit its details for registration and to get a SRN created by Eudamed after validation by a CA	ACT	LR-ACT-001	Article 31(1, 2, 3) Article 30(1) Annex VI Part A Section 1	Article 28(1) Annex VI Part A Section 1
	Update actor own details	Enable manufacturer to update its details within one week of any change	ACT	LR-ACT-006	Article 31(4)	Article 28(4)
	Confirm accuracy of its actor data in Eudamed	Enable manufacturer, no later than 1 year after submission and every second year thereafter, to confirm the accuracy of its actor data in Eudamed	ACT	LR-ACT-004	Article 31(5)	Article 28(5)
Authorised Representative	Submit actor data for registration and for accessing Eudamed	Enable AR to submit its details for registration and to get a SRN created by Eudamed after validation by a CA	ACT	LR-ACT-002	Article 31(1) Annex VI Part A Section 1	Article 28(1) Annex VI Part A Section 1
	Update actor own details	Enable AR to update its details within one week of any change	ACT	LR-ACT-007	Article 31(4)	Article 28(4)
	Confirm accuracy of its actor data in Eudamed	Enable AR, no later than 1 year after submission and every second year thereafter, to confirm the accuracy of its actor data in Eudamed	ACT	LR-ACT-011	Article 31(5)	Article 28(5)
Importer	Submit actor data for registration and for accessing Eudamed	Enable importer to submit its details for registration and to get a SRN created by Eudamed after validation by a CA	ACT	LR-ACT-003	Article 31(1) Annex VI Part A Section 1	Article 28(1) Annex VI Part A Section 1
	Update actor own details	Enable importer to update its details within one week of any change	ACT	LR-ACT-008	Article 31(4)	Article 28(4)
	View actor data	Enable importer to verify that manufacturer and authorised representative have provided their	ACT	LR-ACT-010	Article 30(3)	Article 27(3)

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		actor details to Eudamed				
	Confirm accuracy of its actor data in Eudamed	Enable importer, no later than 1 year after submission and every second year thereafter, to confirm the accuracy of its actor data in Eudamed	ACT	LR-ACT-012	Article 31(5)	Article 28(5)
	Link importer to manufacturer(s) (and devices)	Enable importers to add their details to the relevant entry/entries. Enable importer to verify that the device is registered and add his/her actor details to the registration	ACT	LR-ACT-017	Article 30(3) Article 13(4)	Article 27(3) Article 13(4)
Notified Body	Manage the list of subsidiaries	Enable the Notified bodies to enter the list of their subsidiaries in Eudamed and to make it publicly available through andEudamed.	CRF	LR-CRF-001	Article 37(3) Article 57(1a)	Article 33(3) Article 52(a)
Competent Authority	Download actor data	Allow for export of actor data.	ACT	LR-ACT-016	Article 33(3)	Article 30(3)
	Manage economic operator registration requests for SRN	Enable CA to view and validate data submitted by the economic operator After validation, obtain from Eudamed a single registration number ('SRN') and issue it to the economic operator through Eudamed	ACT	LR-ACT-005	Article 31(2)	Article 28(2)
Commission	Set up, maintain and manage Eudamed	The Commission shall set up, maintain and manage the European database on medical devices ('Eudamed') for the following purposes: (a)to enable the public to be adequately informed about devices placed on the market, the corresponding certificates issued by notified bodies and about the relevant economic operators; Eudamed shall include the following electronic systems: (c) the electronic system on registration of economic operators referred to in Article 30;	EUD	LR-NFS-002	Article 33(1, 2, 8)	Article 30(1)
	Manage NB Actor data	Provide and keep up-to-date in Eudamed NB Actor details data from Nando (NB actor details data to keep it synchronised with the information in Nando (master NB data).	ACT CRF	LR-ACT-015 LR-CRF-011	Article 43(2) Article 57(1d)	Article 39(2) Article 52(d)

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Public	View information on registered economic operators	Make accessible to the public the actor data, which are not personal data, entered in Eudamed about the economic operators. Enable the public to be adequately informed about the relevant economic operators	ACT	LR-ACT-009 LR-ACT-015	Article 31(7) Annex VI Part A Section 1 Article 33(1a)	Article 28(7) Annex VI Part A Section 1 Article 30(1)

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7.2. UDI/DEVICE - UDID

Stakeholder	Stakeholder Task	Eudamed Requirement (Eudamed shall allow/enable)	Module	Requirement ID No	Legal Basis (MDR)	Legal Basis (IVDR)
Manufacturer	Submit Basic UDI-DI and associated UDI-DI data	Enable manufacturer to provide to the UDI database the Basic UDI-DI assigned to a device together with the other UDI-DI core data elements related to that device	UDID	LR-UDID-001	Article 29(1) Annex VI Part B	Article 26(1) Annex VI Part B
		Do not allow entering UDI-PIs and commercially confidential product information	UDID	LR-UDID-011	Article 28(2)	Article 25 in IVDR refers to Article 28 in MDR
	Submit device data	Enable manufacturer to enter device details together or after having submitted Basic UDI-DI and UDI-DI data	UDID	LR-UDID-003	Article 29(4) Annex VI Part A Section 2	Article 26(3) Annex VI Part A Section 2
	Update device data	Enable manufacturer to update device details to keep them up-to-date with changes	UDID	LR-UDID-004	Article 29(4)	Article 26(3)
	View (Basic) UDI-DI data and Device data	Before placing a device on the market, Enable to ensure that the Basic UDI-DI assigned to a device together with the other core data elements related to that device are correctly submitted and transferred to the UDI database Enable to verify device data are well provided and up-to-date	UDID	LR-UDID-010	Article 27(3) Article 29(4)	Article 24(3) Article 26(3)
	Upload of Basic UDI-DI, UDI-DI and device data	Allow for automatic uploads of their own Basic UDI-DI and related UDI-DI data elements and device data	UDID	LR-DTX-001	Article 28(4)	Article 25 in IVDR refers to Article 28 in MDR
	Download of Basic UDI-DI, UDI-DI (including for systems and procedure packs) and device data	Allow for automatic downloads of any registered Basic UDI-DI and related UDI-DI data elements and device data	UDID	LR-DTX-002	Article 28(4)	Article 25 in IVDR refers to Article 28 in MDR

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	Get nomenclature data	Eudamed shall make available the correspondence between the codes that are part of an internationally recognised medical devices nomenclature and their definitions. This information shall be provided up-to-date and free of charge to Manufacturers and other Actors, if justified by their activities in Eudamed.	UDID	LR-UDID-002	Article 26	Article 23
System/Procedure pack Producer	Upload of Basic UDI-DI, and UDI-DI data for systems and procedure packs	Allow for automatic uploads of the Basic UDI-DI and related UDI-DI data elements for their systems and procedure packs	UDID	LR-DTX-007	Article 28(4)	Article 25 in IVDR refers to Article 28 in MDR
	Submit Basic UDI-DI and associated UDI-DI data for a system or a procedure pack	Enable system/procedure pack producer to provide the Basic UDI-DI assigned to a system or procedure pack pursuant to Art 22(1) and (3) together with the other UDI-DI core data elements related to that system or procedure pack	UDID	LR-UDID-007	Article 29(2) Annex VI Part B	N/A
	Download of Basic UDI-DI and UDI-DI (including for systems and procedure packs) and device data	Allow for automatic downloads of any registered Basic UDI-DI and related UDI-DI data elements	UDID	LR-DTX-002	Article 28(4)	Article 25 in IVDR refers to Article 28 in MDR
	Get nomenclature data	Eudamed shall make available the correspondence between the codes that are part of an internationally recognised medical devices nomenclature and their definitions. This information shall be provided up-to-date and free of charge to Manufacturers and other Actors, if justified by their activities in Eudamed.	UDID	LR-UDID-002	Article 26	Article 23
Authorised Representative	Download of Basic UDI-DI, UDI (including for systems and procedure packs) and device data	Allow for automatic downloads of any registered Basic UDI-DI and related data elements	UDID	LR-DTX-003	Article 28(4)	Article 25
	Search and View Device and UDI-DI data	Enable to verify that the manufacturer has complied with the registration obligations laid down in Articles 27 [UDI-DI data] and 29 [Device	UDID	LR-UDID-013	Article 11(3c)	Article 11(3c)

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		data]				
Importer	Link importer to manufacturer(s) (and devices)	Enable importer to add their details to the relevant entry/entries. Enable to verify that the device is registered and add his/her actor details to the registration	ACT	LR-UDID-005	Article 30(3) Article 13(4)	Article 27(3) Article 13(4)
	View UDI and device data	Enable to verify that the manufacturer or authorised representative has provided his/her actor details	UDID	LR-UDID-005	Article 13(4)	Article 13(4)
	Download of Basic UDI-DI, UDI (including for systems and procedure packs) and device data	Allow for automatic downloads of any registered Basic UDI-DI and related data elements (UDI-DI and device data)	UDID	LR-DTX-004	Article 28(4)	Article 25
Notified Body	Confirm certificate identification in device data	Enable to confirm in Eudamed that the information related to the certificate identification for the device is correct	UDID	LR-UDID-006	Article 29(3) Annex VI Part A Section 2.2	Article 26(3) Annex VI Part A Section 2.2
	Upload SS(C)P	After its validation, enable the notified body to upload the Summary of Safety (and Clinical) Performance (SS(C)P) and enter its meta-data to related device data	CRF	LR-CRF-021	Article 32(1), 57(1i) Annex VI Part A Section 2.14	Article 29(1), 52(i) Annex VI Part A Section 2.11
	Download of Basic UDI-DI, UDI (including for systems and procedure packs) and device data	Allow for automatic downloads of any registered Basic UDI-DI and related data elements (UDI-DI and device data)	UDID	LR-DTX-005	Article 28(4)	Article 30(1) Article 25
Competent Authority	Download of Basic UDI-DI, UDI (including for systems and procedure packs) and device data	Allow for automatic downloads of the Basic UDI-DI, UDI-DI and related data elements and device data	UDID	LR-DTX-006	Article 33(3) Article 28(4)	Article 30(1) Article 25
Commission	Set up, maintain and manage Eudamed	The Commission shall set up, maintain and manage the European database on medical devices ('Eudamed') for the following purposes: (a)to enable the public to be adequately informed about devices placed on the market, the corresponding certificates issued by notified bodies and about the relevant economic	EUD	LR-NFS-002	Article 33(1, 2, 8) Article 28(4)	Article 30(1) Article 25 in IVDR refers to Article 28 in MDR

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		operators; (b)to enable unique identification of devices within the internal market and to facilitate their traceability; Eudamed shall include the following electronic systems: (a)the electronic system for registration of devices referred to in Article 29(4)/26(3); (b)the UDI-database referred to in Article 28/25; Allow for downloading of the Basic UDI-DI and related UDI-DI and device data elements				
Public	View SS(C)P attached to a registered device	Make the summary of safety [and clinical] performance (SS(C)P) available to the public via Eudamed	UDID	LR-CRF-022	Article 32(1)	Article 29(1)
	Download registered Basic UDI-DI and UDI-DI data	Allow for extract of the Basic UDI-DI and UDI-DI related data	UDID	LR-DTX-008	Article 28(4)	Article 25 in IVDR refers to Article 28 in MDR
	View information on the registered Basic UDI-DI, UDI-DI and Device	Eudamed shall enable the public to be adequately informed about devices placed on the market	UDID	LR-UDID-015	Article 33(1a)	Article 30(1)
	View information on the registered Basic UDI-DI, UDI-DI	Make the core data elements to be provided to the UDI database accessible to the public free of charge The user interface of the UDI database shall be available in all official languages of the Union	UDID	LR-UDID-009	Article 28(3) Annex VI Part B Annex VI Part C 5.10	Article 25 in IVDR refers to Article 28 in MDR Annex VI Part B

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7.3. Certificate & Notified Body - CRF

Stakeholder	Stakeholder Task	Eudamed Requirement (Eudamed shall allow/enable)	Module	Requirement ID No	Legal Basis (MDR)	Legal Basis (IVDR)
Notified Body	Inform about refusal or withdrawal of an application	Enable to enter a refusal of a manufacturer's application for conformity assessment. Make accessible to other NBs the refusal of application	CRF	LR-CRF-006	Annex VII(4.3) Article 57(1g)	Annex VII(4.3) Article 52(g)
		Enable to enter a withdrawal of a manufacturer's application prior the NB's decision regarding the conformity assessment to inform other NBs of the withdrawal. Notify other NBs of withdrawal of an application. Make accessible withdrawal of application to other NBs.	CRF	LR-CRF-015	Article 53(2) Annex VII(4.3) Article 57(1g)	Article 49(2) Annex VII(4.3) Article 52(g)
	Notify applicability of CECP	Enable to notify CAs/DAs/Commission as to whether a CECP (for certain class III and class IIb devices) is to be applied when performing the conformity assessment of the device and provide the clinical evaluation assessment report.	CRF	LR-CRF-002	Article 54(3) Article 57(1f)	-
	Transmit clinical evaluation information	Enable to enter the clinical evaluation assessment report and the MF's clinical evaluation documentation to transmit them to the COM.	CRF	LR-CRF-009	Annex IX(5.1a)	-
	Provide full justification where NB has not followed the advice of the expert panel	Enable the NB to provide full justification where it has not followed the advice of the expert panel in its conformity assessment report	CRF	LR-CRF-027	Annex IX(5.1g)	-
	Provide required information on mechanism for scrutiny	Enable to notify CAs/Authorities responsible for NBs (DAs) about certificates granted to devices for which a clinical evaluation consultation procedure (CECP) has been performed (for certain class III and class IIb devices) / to class D devices and provide the required information	CRF	LR-CRF-010	Article 55(1) Article 57(1f)	Article 50(1) Article 52(f)
	Enter information on certificates and refused certificates	Enable the notified body to enter in Eudamed any information regarding certificates issued, including amendments and supplement thereto, and	CRF	LR-CRF-003	Article 56(5) Article 57(1h)	Article 51(5) Article 52(h)

		regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates.				
		The minimum content of the certificate shall be as defined in Chapter II of Annex XII (but not all has to be as meta-data in Eudamed).	CRF	LR-CRF-019	Annex XII(Chapter II)	Annex XII(Chapter II)
	View information on certificates and related information	Where public and/or data to which they are associated, enable to view information collated and processed in electronic system (Eudamed module) on NBs and on certificate on conformity	CRF	LR-CRF-026	Article 57(2)	Article 42(7)
Expert Panel (user profile under Commission)	Notify decision to provide Scientific Opinion or not	Enable to notify the Commission whether it intends to provide a scientific opinion for a CECP assigned to this Expert Panel.	CRF	LR-CRF-013	Annex IX.5.1e	-
	Notify reasons for not providing Scientific Opinion.	Enable to notify the Commission and the NB the reasons for its decision not to provide a scientific opinion.	CRF	LR-CRF-020	Annex IX.5.1d	-
	Provide Scientific Opinion.	Enable to provide a scientific opinion on the clinical evaluation assessment report of a device.	CRF	LR-CRF-017	Annex IX.5.1.c	-
Competent Authority (including Authority responsible for NBs)	Download certificate data	Enable to export certificate data.	CRF	LR-CRF-016	Article 33(3)	Article 30(3)
	View information collated and processed by Eudamed for NBs and certificates	Make accessible to all competent authorities all the information collated and processed by the electronic system on NBs and certificates of conformity (NB & certificate Eudamed module)	CRF	LR-CRF-007	Article 57(2)	Article 52(2)
Authority responsible for NBs (DA)	Upload a Summary Report regarding NBs.	Enable to upload Summary Report of monitoring and on-site assessment activities regarding the NBs	CRF	LR-CRF-014	Article 44(12) Article 57(1e)	Article 40(12) Article 52(e)
	Enter information on required suspension or withdrawal of certificates	Enable to enter information in relation to certificates of which designating authority has required their suspension or withdrawal	CRF	LR-CRF-023	Article 46(7d)	Article 42(7d)
	Inform CAs about required withdrawal or suspension of certificates	Enable to inform the CAs of the MS in which the MF has its registered place of business about certificates for which suspension or withdrawal has been required	CRF	LR-CRF-025	Article 46(7e)	Article 42(7e)

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Commission	Set up, maintain and manage Eudamed	The Commission shall set up, maintain and manage the European database on medical devices ('Eudamed') for the following purposes: (a)to enable the public to be adequately informed about devices placed on the market, the corresponding certificates issued by notified bodies and about the relevant economic operators; Eudamed shall include the following electronic systems: (d)the electronic system on notified bodies and on certificates referred to in Article 57/52;	EUD	LR-NFS-002	Article 33(1, 2, 8)	Article 30(1)
	Database controller	Provide and keep up-to-date NB data and NB notifications, including accompanying docs and objection/opinion docs) to keep it synchronised with the information in NANDO (master NB data).	CRF	LR-CRF-011	Article 42(10) Article 46(1) Article 46(2) Article 57(1c)	Article 38(10) Article 42(1) Article 42(2) Article 52(c)
	Manage list of nominated experts.	Enable to maintain a list of nominated experts for joint assessment of applications for notifications in order to make it publicly available to Member States competent authorities.	CRF	LR-CRF-008	Article 40(2) Article 57(1b)	Article 36(2) Article 52(b)
	Manage list of expert panels	Enable to maintain a list of expert panels that can provide a scientific opinion for clinical evaluation consultation procedure	CRF	LR-CRF-024	Annex IX.5.1	-
	Manage NB Actor data	Enable to provide and keep up-to-date NB Actor data (NB data and NB notifications, including accompanying docs and objection/opinion/response docs) to keep it synchronised with the information in NANDO (master NB data).	CRF	LR-CRF-011	Article 42(10) Article 46(1) Article 46(2) Article 57(1c)	Article 38(10) Article 42(1) Article 42(2) Article 52(c)
	Assign an Expert Panel to a CECP	Enable to assign an expert panel and transmit to the expert panel the clinical evaluation assessment report and the MF's clinical evaluation documentation information for consultation (Scientific Opinion).	CRF	LR-CRF-012	Annex IX.5.1a	-

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	Make both the scientific opinion of the expert panel and the justification of the NB publicly available	EC shall through Eudamed make available to the public both the expert panel opinion and the written justification provided by the NB in case the NB did not follow the advice of the expert panel in its conformity assessment report	CRF	LR-CRF-028	Annex IX.5.1g	-
	View information collated and processed by Eudamed for NBs and certificates	Make accessible to the Commission all the information collated and processed by the electronic system on NBs and certificates of conformity (NB & certificate Eudamed module)	CRF	LR-CRF-007	Article 57(2)	Article 52(2)
Public	View information on the certificates, refused certificate and the NBs Search for information	Eudamed shall enable the public to be adequately informed about the corresponding certificates issued by notified bodies. Enable to view information about issued certificates (certificates issued, including amendments and supplements thereto, and regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates) and their updates, refused certificates, SSCP/SSP, NBs (NB numbers, conformity assessment activities, and types of devices), list of NB's subsidiaries and Summary of monitoring activities performed by MSs	CRF	LR-CRF-018	Article 33(1a) Article 57(2) Article 56(5) Article 44(12)	Article 30(1) Article 42(7) Article 51(5) Article 40(12)
	View expert panel opinions on CECPs and justifications of the NB for not following the expert panel advice	Enable the public to view the expert panel opinion and the written justification provided by the NB in case the NB did not follow the advice of the expert panel in its conformity assessment report	CRF	LR-CRF-029	Annex IX.5.1g	-

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7.4. Clinical Investigation - CIPS

Stakeholder	Stakeholder Task	Eudamed Requirement (Eudamed shall allow/enable)	Module	Requirement ID No	Legal Basis (MDR)	Legal Basis (IVDR)
Sponsor	Submit application for CI/PS with all required data and documentation	Enable submission of application to the MS(s) where the CI/PS will be conducted together with all relevant data and documentation as per the requirements of Chapter II of Annex XV of MDR / Section 2 and 3 of Annex XIII and in Annex XIV of IVDR	CIPS	LR-CIPS-001	Article 70(1) Annex XV Chapter II Article 73(1b)	Article 66(1) Annex XIII Section 2 and 3 Annex XIV Article 69(1b)
		Enable submission of application for CI/PS, to assess outside the scope of its intended purpose, a device which already bears the CE marking, to the MS(s) where the CI/PS will be conducted, together with all relevant data and documentation.	CIPS	LR-CIPS-009	Article 74(2) Article 70(1) Annex XV Chapter II Article 73(1b)	Article 70(2) Article 66(1) Annex XIII Section 2 and 3 Annex XIV Article 69(1b)
		Generate a Union-wide unique single identification number (CI/PS SIN) for the CI/PS, which shall be used for all relevant communication in relation to that CI/PS	CIPS	LR-CIPS-010	Article 70(1) Article 73(1a)	Article 66(1) Article 69(1a)
		Enable submission of a single application for CI/PS to be conducted in more than one MS that, upon receipt, is transmitted electronically to all MSs in which the CI/PS is to be conducted.	CIPS	LR-CIPS-012	Article 78(1) Article 70(1) Article 73(1b)	Article 74(1) Article 66(1) Article 69(1b)
		Enable proposing, in the case of a single application for CI/PS to be conducted in more than one MS, the Coordinating MS (CMS) among the MSCs.	CIPS	LR-CIPS-002	Article 78(2) Article 70(1) Article 73(1b)	Article 74(2) Article 66(1) Article 69(1b)
	Notify MSC(s) for PMCF/PMPF investigation/study	Enable notification of PMCF/PMPF investigation/study to the MSC(s) at least 30 days prior to its commencement with all the required data and documentation	CIPS	LR-CIPS-003	Article 74(1) Annex XV Chapter II Article 73(1b)	Article 70(1) Annex XIII Part ASection 2 Annex XIV Article 69(1b)

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	Notify substantial modifications to CI/PS or PMCF/PMPF	Enable notification of substantial modifications to CI/PS or PMCF/PMPF to the MS(s) in which the CI/PS or PMCF/PMPF is being or is to be conducted (all MSC(s)) of the reasons for and the nature of those modifications with the updated data and documentation in a new version of the required data and documentation. Changes shall be clearly identifiable between former and new version.	CIPS	LR-CIPS-004	Article 74(1) Article 75(1) Article 76(1) Article 78(12) Annex XV Chapter II Article 73(1b)	Article 70(1) Article 71(1) Article 72(1) Article 74(12) Annex XIV Article 69(1b)
	Update relevant data of application for CI/PS	Enable to update the relevant data within one week of any change occurring to the application data and documentation and make that change clearly identifiable. The MSC(s) shall be notified of the update.	CIPS	LR-CIPS-005	Article 70(2) Annex XV Chapter II Article 73(1b)	Article 66(2) Annex XIV Chapter I Article 69(1b)
	Comment or complete application for CI/PS within the time limit sets by the MS	Enable to comment or complete application for CI/PS within the time limit set by the MS after the MS has informed the sponsor that the CI/PS applied for does not fall within the scope of this Regulation or that the application dossier is not complete.	CIPS	LR-CIPS-006	Article 70(3) Article 73(1b)	Article 66(3) Article 69(1b)
	Provide additional information requested by the MS	Enable to provide additional information requested by the (C)MS within the time set by the MSC during the period when the application is being assessed	CIPS	LR-CIPS-007	Article 70(6) Article 78(5)	Article 66(6) Article 74(5)
	Withdraw application for CI/PS or PMCF/PMPF	Enable to indicate that application for CI/PS or PMCF/PMPF is withdrawn by the sponsor prior to a decision by a MS	CIPS	LR-CIPS-008	Article 74(1) Article 76(4)	Article 70(1) Article 72(4)
	Inform MSC(s) of the temporary halt or early termination of CI/PS or PMCF/PMPF	Enable to inform the MS in which CI/PS or PMCF/PMPF (MSC(s)) has been temporarily halted or terminated early, providing a justification	CIPS	LR-CIPS-018	Article 74(1) Article 77(1) Article 76(1,3) Article 73(1d)	Article 70(1) Article 73(1) Article 72(1, 3) Article 69(1d)
	Notify each MSC(s) of the end of CI/PS or PMCF/PMPF	Enable to notify each/all MS(s) in which a CI/PS or PMCF/PMPF was being conducted of the end of that CI/PS in that MS (MSC(s)). That notification shall be made within 15 days of the end of the CI/PS or PMCF/PMPF.	CIPS	LR-CIPS-020	Article 74(1) Article 77(3,4) Article 73(1d)	Article 70(1) Article 73(3,4) Article 69(1d)

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	Submit CI/PS or PMCF/PMPF outcome report with its summary	Enable to submit to the MSC(s) CI/PS or PMCF/PMPF outcome report accompanied by a summary irrespectively of the outcome (end, early termination or temporary halt) within one year of the end or within 3 months of the early termination or temporary halt. Enable inform for later date of submission of CI/PS or PMCF/PMPF report with justifications, due to scientific reasons, as well as specify date of provision of the report and summary and justification for the delay in CI/PS plan document stored in Eudamed.	CIPS	LR-CIPS-022	Article 74(1) Article 77(5) Annex XV Chapter I Section 2.8 Chapter III Section 7 Article 73(1d)	Article 70(1) Article 73(5) Annex XIII Part A Section 2.3.3 Article 69(1d)
	Report to all MSC(s) serious adverse event or device deficiency that occurs during CI/PS (not during PMCF investigation / PMPF study)	Enable to report without delay to all MSC(s) any serious adverse event or any device deficiency that might have led to a serious adverse event that occurs during CI/PS, also those that occurred in third countries in which a CI/PS is performed under the same CI/PS plan as one applying to a CI/PS covered by MDR/IVDR. As of 26 May 2020, enable to report serious adverse event or any device deficiency that occurs in CI that have started prior to 26 May 2020 to be conducted in accordance with MD Directives. Enable reporting of serious adverse event or device deficiency that occurs during PMCF investigation / PMPF study (vigilance provisions applies, incident report instead). To ensure timely reporting, enable submission of an initial report that is incomplete followed up by a complete report. Upon receipt, transmit electronically the report to all MSC(s).	CIPS	LR-CIPS-023	Article 80 (2a,b, 3, 4, 5) Article 73 (1e) Article 122(11)	Article 76 (2a,b, 3, 4, 5) Article 69(1e)

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	Report to all MSC(s) any new findings/updates on already reported serious adverse event or device deficiency that occurs during CI/PS	Enable to report without delay to all MSC(s) any new findings/updates on already reported serious adverse event or device deficiency that occurs during CI/PS, also those that occurred in third countries in which a CI/PS is performed under the same CI/PS plan as one applying to a CI/PS covered by MDR/IVDR. As of 26 May 2020, enable to any new findings/updates on already reported serious adverse event or device deficiency that occurs in CI that have started prior to 26 May 2020 to be conducted in accordance with MD Directives. Upon receipt, transmit electronically the new findings/updates to all MSC(s).	CIPS	LR-CIPS-024	Article 80 (2c, 3, 4, 5) Article 73 (1e) Article 120(11)	Article 76 (2c, 3, 4, 5) Article 69(1e)
Competent Authority	Access all information available in Eudamed about CI/PS	Exchange of information between the MS and between them and the Commission (content from Article 73 (1c) of MDR / Article 69 (1c) of IVDR) shall only be accessible to the MS and the Commission. All other information referred to in Article 73 (1) of MDR / Article 69 (1) about CI/PS shall be accessible to all unless confidentiality of the information is justified (personal data protection, commercially confidential information, effective supervision by MS).	CIPS	LR-CIPS-035	Article 73(3) Article 73(1)	Article 69(3) Article 69(1)
	Notify the sponsor of its decision on the validation of an application for CI/PS	Enable the MSC(s), and if applicable the CMS, to notify the sponsor of its decision on the validation of an application for CI/PS as to whether the CI/PS falls within the scope of the MDR/IVDR and as to whether the application dossier is complete. Validation date of the application is set from the date on which the sponsor is notified.	CIPS	LR-CIPS-026	Article 70(1,5) Article 78(3, 4c) Annex XV Chapter II	Article 66(1,5) Article 74(3,4c) Annex XIV Chapter I

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	Inform and set the time limit for the sponsor to comment the MS decision or to complete the application dossier	Enable the MS to inform the sponsor on the time limit and to set this time limit in accordance with the MDR/IVDR to comment the MS decision that the CI/PS does not fall within the scope of the MDR/IVDR or to complete the application dossier.	CIPS	LR-CIPS-027	Article 70(3) Article 78(3, 4c)	Article 66(3) Article 74(3, 4c)
	Extend the time limit for the sponsor to comment the MS decision or to complete the application dossier	Enable the MS, and if applicable the CMS, to inform the sponsor of an extension of the time limit to comment the MS negative decision (not falling within the scope) or complete the application dossier and to set this time limit in accordance with the MDR/IVDR (max 20 days).	CIPS	LR-CIPS-028	Article 70(3) Article 78(3, 4c)	Article 66(3) Article 74(3, 4c)
	Extend the time limit for the MS to notify its validation	Enable the MS, and if applicable the CMS, to inform the sponsor of an extension of the time limit and to set this time limit in accordance with the MDR/IVDR (max 5 days) for the MS to notify its validation decision on a CI/PS either after first submission of application by the sponsor or after having received by the sponsor its comments or a completed application .	CIPS	LR-CIPS-025	Article 70(4) Article 78(4c)	Article 66(4) Article 74(4c)
	Notify the sponsor of its decision on the validation of an application for CI/PS after reception of comments or of the requested additional information	Enable the MSC(s), and if applicable the CMS, to notify the sponsor, within 5 days of receipt of the comments or of the additional information, of its decision on the validation of an application for CI/PS as to whether the CI/PS falls within the scope of the MDR/IVDR and as whether the application dossier is complete. Validation date of the application is set from the date on which the sponsor is notified.	CIPS	LR-CIPS-029	Article 70(3, 5) Article 78(3, 4c) Annex XV Chapter II	Article 66(3, 5) Article 74(3, 4c) Annex XIV Chapter I
	Request additional information from the sponsor during the CI/PS assessment process by MSC(s), and if applicable by the CMS	Enable the MSC(s), and if applicable the CMS, to request additional information from the sponsor during the period when the application is being assessed	CIPS	LR-CIPS-030	Article 70(6) Article 78(5)	Article 66(6) Article 74(5)

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	Notify the sponsor of the authorisation for a CI/PS	Enable the MSC(s), and if applicable the CMS, to notify the sponsor of the authorisation within 45 days of the validation date (extended automatically when requesting additional information by the time it takes to receive the additional information from the sponsor). Each MSC participating in a coordinated assessment shall notify the sponsor whether it is authorised subject to conditions, or whether authorisation has been refused, and this as one single decision within 5 days of the transmission of the final assessment report by the CMS.	CIPS	LR-CIPS-031	Article 70(7b) Article 70(6) Article 76(3) Article 78(11) Article 78(5)	Article 66(7b) Article 66(6) Article 72(3) Article 74(11) Article 74(5)
	Extend the period for notification of the authorisation for a CI/PS	Enable the MSC(s), and if applicable the CMS, to extend the period of 45 days for notification of the authorisation by a further 20 days for the purpose of consulting with experts, or by a further 50 days if by CMS for class IIb/C and class III/D device.	CIPS	LR-CIPS-032	Article 70(7b) Article 78 (6)	Article 66(7b) Article 74(6)
	Notify the sponsor of the refusal of modifications to CI/PS	Enable the MSC(s), and if applicable the CMS, to notify the sponsor of the refusal of modifications to CI/PS notified by a sponsor, together with its justification and/or an Ethic Committee negative opinion.	CIPS	LR-CIPS-036	Article 75(3)	Article 71(3)
	Extend the period for notification of the refusal for substantial modifications to CI/PS or PMCF/PMPF	Enable the MSC(s), and if applicable the CMS, to extend the period of maximum 7 days for (authorisation or) notification by the CA of a possible refusal of the substantial modifications notified by the sponsor.	CIPS	LR-CIPS-037	Article 74(1) Article 75(4)	Article 70(1) Article 71(4)
	Notify the sponsor that it is the CMS	Enable the MS to notify the sponsor, within 6 days of receipt of the single application, that it is the CMS for this single application for CI/PS. In case of no agreement/notification of the MS on a CMS, the CMS proposed by the sponsor shall assume that role. Enable the Notification date to be set at the date on which the notification is submitted or at the end of the 6 days of receipt.	CIPS	LR-CIPS-043	Article 78(4a) Article 78(2)	Article 74(4a) Article 74(2)

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	Submit considerations for the purpose of the validation of a CI/PS application following the coordinated assessment procedure	Enable the MSCs to submit within 7 days of the notification date any considerations for the purpose of validation of a CI/PS application following the coordinated assessment procedure	CIPS	LR-CIPS-044	Article 78(4b)	Article 74(4b)
	Transmit draft assessment report by the CMS of a CI/PS following the coordinated assessment procedure	Enable the CMS of a CI/PS following the coordinated assessment procedure to transmit its draft assessment report within 26 days of the validation date, to the other MSCs	CIPS	LR-CIPS-045	Article 78(4d)	Article 74(4d)
	Transmit comments and proposals on the draft assessment report of a CI/PS following the coordinated assessment procedure to the CMS	Enable the MSCs to transmit to the CMS within 38 days of the validation date any comments and proposals on the draft assessment report made by the CMS of a CI/PS following the coordinated assessment procedure and the underlying application	CIPS	LR-CIPS-047	Article 78(4d)	Article 74(4d)
	Transmit final assessment report by the CMS of a CI/PS following the coordinated assessment procedure for CI/PS	Enable the CMS of a CI/PS following the coordinated assessment procedure for CI/PS to transmit its final assessment report, taking due account of comments an proposals received from MSCs, within 45 days of the validation date, to the sponsor and the other MSCs.	CIPS	LR-CIPS-048	Article 78(4d)	Article 74(4d)
	Communicate its disagreement on the conclusion of the CMS concerning the area of coordinated assessment of CI/PS	Enable MSC to communicate its disagreement on the conclusion of the CMS concerning the area of coordinated assessment, together with a detailed justification, to the Commission, to all other MSCs and to the sponsor, Prevent disagreement where the conclusion of the CMS is that the CI/PS is not acceptable concerning the area of coordinated assessment.	CIPS	LR-CIPS-046	Article 78 (8, 9, 12)	Article 74 (8, 9, 12)

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	Coordinate assessment of serious adverse events and device deficiencies	Enable Competent Authorities and the CMS associated to the CI/PS to coordinate their assessment of serious adverse events and device deficiencies to determine whether to modify, suspend or terminate the clinical investigation or whether to revoke the authorisation for that clinical investigation	CIPS	LR-CIPS-034	Article 80(4)	Article 76(4)
	Inform on whether the MS agrees to apply the coordinated assessment procedure for CI/PS	Enable to inform on whether the MS agrees to apply the coordinated assessment procedure for CI/PS or not. After 26 May 2027 for MDR, 2029 for IVDR, all MS shall be required to apply that procedure.	CIPS	LR-CIPS-033	Article 78(14) Article 123(3h)	Article 74(14) Article 113(3g)
	Communicate decisions and grounds on measures taken at national level for CI/PS or PMCF/PMPF, refused CI/PS or PMCF/PMPF, early termination of CI/PS or PMCF/PMPF on safety grounds notified by a sponsor or withdrawn of application by a sponsor prior to a decision by the MS.	Enable to communicate to all MS and the Commission the corresponding decision and the grounds on corrective measure taken on its territory for CI/PS or PMCF/PMPF as revoke authorisation, suspend or terminate CI/PS or PMCF/PMPF, require the sponsor to modify CI/PS or PMCF/PMPF, refusal of CI/PS or PMCF/PMPF, notification by a sponsor of the early termination of a CI/PS or PMCF/PMPF on safety grounds and application withdrawn by a sponsor prior to a decision by the MS	CIPS	LR-CIPS-039	Article 74(1) Article 76(3) Article 76(1) Article 76(4) Article 73(1c)	Article 70(1 Article 72(3) Article 72(1) Article 72(4) Article 69(1c)
Commission	Access all information available in Eudamed about CI/PS	Exchange of information between the MS and between them and the Commission (content from Article 73 (1c) of MDR / Article 69 (1c) of IVDR) shall only be accessible to the MS and the Commission. All other information referred to in Article 73 (1) of MDR / Article 69 (1) about CI/PS shall be accessible to all unless confidentiality of the information is justified (personal data protection, commercially confidential information, effective supervision by MS).	CIPS	LR-CIPS-035	Article 73(3) Article 73(1)	Article 69(3) Article 69(1)

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	Set up, maintain and manage Eudamed	The Commission shall set up, maintain and manage the European database on medical devices ('Eudamed') for the following purposes: (c)to enable the public to be adequately informed about clinical investigations and to enable sponsors of clinical investigations to comply with obligations under Articles 62 to 80, Article 82, and any acts adopted pursuant to Article 81; (e)to enable the competent authorities of the Member States and the Commission to carry out their tasks relating to this Regulation on a well-informed basis and to enhance the cooperation between them Eudamed shall include the following electronic systems: (e) the electronic system on clinical investigations/performance study referred to in Article 73/69;	EUD	LR-NFS-002	Article 33(1, 2, 8)	Article 30(1)
		The user interface of the CI/PS module in Eudamed shall be available in all official languages of the Union	CIPS	LR-CIPS-011	Article 73(5)	Article 69(5)
		Interoperability with the EU database for clinical trials on medicinal products for human use set up in accordance with Article 81 of Regulation (EU) No 536/2014 as concerns combined CI of devices under MDR with a clinical trial under that Regulation or PS of companion diagnostic under IVDR.	CIPS	LR-CIPS-038	Article 73(2)	Article 69(2)
	Database controller	No personal data of subjects shall be publicly available.	CIPS	LR-CIPS-059	Article 73(3) Article 73(1) Article 73(4)	Article 69(3) Article 69(1) Article 69(4)

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Public	Access to summary and CI/PS report on the outcome of CI/PS or PMCF/PMPF	The summary and the CI/PS report shall become publicly accessible through Eudamed at the latest when the device is registered in Eudamed and before it is placed on the market. In case of early termination or temporary halt, the summary and the report shall become publicly accessible immediately after submission. If the device is not registered in Eudamed within one year of the summary and the report having been entered in Eudamed, they shall become publicly accessible at that point in time.	CIPS	LR-CIPS-058	Article 74(1) Article 77(7) Article 73(1d)	Article 70(1) Article 73(7) Article 69(1d)
	Access to publicly available information for CI/PS	All information referred to in Article 73 (1) of MDR / Article 69 (1) about CI/PS, except exchange of information between the MS and between them and the Commission (content from Article 73 (1c) of MDR / Article 69 (1c) of IVDR), shall be accessible through Eudamed to all unless for all or parts confidentiality of the information is justified (personal data protection, commercially confidential information, effective supervision by MS).	CIPS	LR-CIPS-057	Article 73(3)	Article 69(3)

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7.5. Vigilance – VGL

Stakeholder	Stakeholder Task	Eudamed Requirement (Eudamed shall allow/enable)	Module	Requirement ID No	Legal Basis (MDR)	Legal Basis (IVDR)
Manufacturer	Submit Periodic Safety Update Reports (PSURs)	Enable submission of PSURs for [class III or implantable medical devices]/[class D in vitro diagnostic devices] to the NB involved in the conformity assessment of the devices	VGL	LR-VGL-001	Article 86(2) Article 92(1d)	Article 81(2) Article 87(1d)
	Report a Serious Incident (SI)	Enable to report to the relevant CA(s) a SI occurring within the Union market for a device made available on the Union market (also before MDR and IVDR dates of application).	VGL	LR-VGL-002	Article 87(1a) Article 92(1a) Article 83(4) Article 120(3)	Article 82(1a) 87(1a), 78(4) Art 110(3)
		Transmit the reported SI (for all legislations and before) to the CA of the MS where the incident occurred and to the NB(s) that issued the certificate(s) of the concerned device where applicable (only MDR/IVDR).	VGL	LR-VGL-003	Article 92(5) Article 92(9)	Article 87(5) Article 87(9)
		Enable the submission of an initial incomplete SI report in order to ensure timely reporting, and then allow update of the report (follow-up) to complete it later	VGL	LR-VGL-004	Article 87(6)	Article 82(6)
		Enable to provide to the CA a final report on a reported serious incident	VGL	LR-VGL-012	Article 89(5) Article 92(1a)	Article 84(5) Article 87(1a)
	Report a Field Safety Corrective Action (FSCA)	Enable to report a FSCA for devices made available in the Union market (also before MDR and IVDR dates of application), including FSCA undertaken in a third country if the reason for the FSCA is not limited to the devices made available in the third country.	VGL	LR-VGL-005	Article 87(1b) Article 87(8) Article 92(1a) Article 83(4) (+Art 120(3))	Article 82(1b) Article 82(8) Article 87(1a) Article 78(4) (+Art 110(3))
		Transmit the reported FSCA to the CAs of the MSs in which the FSCA is being or to be undertaken, to the CA of the MS where the MF is established, and to the NB(s) that issued the certificate(s) of the concerned device.	VGL	LR-VGL-006	Article 92(7) Article 92(9)	Article 87(7) Article 87(9)

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		Enable to provide to the CA a final report on a reported FSCA.	VGL	LR-VGL-028	Article 89(5) Article 92(1a)	Article 84(5) Article 87(1a)
	Submit/Enter a Field Safety Notice (FSN)	Enable the submission of a FSN relating to FSCA(s).	VGL	LR-VGL-013	Article 89(8) Article 92(1e)	Article 84(8) Article 87(1e)
	Submit PSR	Enable the submission of a PSR for similar SIs that occur for the same device/device type and for which the root cause has been identified or a FSCA has been implemented or for incidents that are common and well documented.	VGL	LR-VGL-007	Article 87(9) Article 92(1b)	Article 82(9) Article 87(1b)
		Transmit the submitted PSR to the concerned CA(s)* and to the NB(s) that issued the certificate(s) of the concerned device. * The CA (when the incidents occurred only in one MS) or the CAs in agreement with the PSR possibility and participating in a coordinated assessment (when the incidents occurred in two or more MSs), and the CA of the MS in which the MF is established.	VGL	LR-VGL-008	Article 92(8) Article 92(9)	Article 87(8) Article 87(9)
	Submit a Trend Report (TR)	Enable submission of a TR (report any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side effects that could have a significant impact on the benefit-risk analysis).	VGL	LR-VGL-009	Article 88(1) Article 92(1c)	Article 83(1) Article 87(1c)
		Transmit submitted TR to the CA(s) of the MS where the incident on which the trend is based and to the NB(s) that issued the certificate(s) of the concerned device(s).	VGL	LR-VGL-011	Article 92(6) Article 92(9)	Article 87(6) Article 87(9)
Notified Body	Add its evaluation to PSURs submitted by manufacturers	Enable to view and add its evaluation of PSURs for [class III or implantable medical devices]/[class D in vitro diagnostic devices] submitted by a manufacturer to this NB.	VGL	LR-VGL-014	Article 86(2)	Article 81(2)

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	View post-market surveillance and vigilance information for devices for which they issued certificates	Enable to access all the information on post-market surveillance and vigilance available in Eudamed for devices for which they issued the certificate(s).	VGL	LR-VGL-015	Article 92(2)	Article 87(2)
Competent Authority	View PSURs for [class III or implantable devices]/[class D devices]	Enable to access PSURs available in Eudamed as soon as submitted by the manufacturer, including the evaluation of the NB when available, for [class III or implantable devices]/[class D devices].	VGL	LR-VGL-016	Article 86(2)	Article 81(2)
	Provide TR assessment outcome	Enable to provide assessment report on one or more trend reports and including measures to ensure public health and safety. The assessment report is made available to all CAs and the Commission.	VGL	LR-VGL-017	Article 88(2)	Article 83(2)
	Exchange of information on the evaluation of a reported serious incident and/or FSCA	Enable to provide the outcome of its assessment for incidents and FSCAs including corrective action taken or envisaged by the manufacturer or required of it and to inform the other CAs.	VGL	LR-VGL-019	Article 89(7) Article 92(1f)	Article 84(7) Article 87(1f)
		Enable to inform the manufacturer, other CAs and the Commission it has assumed the role of Coordinating Competent Authority (CCA) for the assessment of serious incident reports and/or FSCAs.	VGL	LR-VGL-020	Article 89(9) Article 92(1e)	Article 84(9) Article 87(1e)
	View all information in Eudamed relating to post-market surveillance and vigilance	Make available all the information in Eudamed, relating to post-market surveillance and vigilance, to the CAs of the Member States and to the Commission.	VGL	LR-VGL-021	Article 92(2)	Article 87(2)
Commission	View/Access all information available in Eudamed about vigilance and post-market surveillance	Make available all the information in Eudamed, relating to post-market surveillance and vigilance, to the CAs of the Member States and to the Commission.	VGL	LR-VGL-021	Article 92(2)	Article 87(2)

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	Set up, maintain and manage Eudamed	The Commission shall set up, maintain and manage the European database on medical devices ('Eudamed') for the following purposes: (d)to enable manufacturers to comply with the information obligations laid down in Articles 87 to 90 or in any acts adopted pursuant to Article 91; (e)to enable the competent authorities of the Member States and the Commission to carry out their tasks relating to this Regulation on a well-informed basis and to enhance the cooperation between them Eudamed shall include the following electronic systems: (f)the electronic system on vigilance and post-market surveillance referred to in Article 92; The Commission shall give due consideration to compatibility with national databases and national web-interfaces to allow for import and export of data.	EUD	LR-NFS-002	Article 33(1, 2, 8)	Article 30(1)
	Analysis of vigilance data in Eudamed	Actively monitor the vigilance and post-market surveillance data in Eudamed in order to identify trends, patterns and signals that may reveal new risks or safety concerns to be communicated to the Commission and the CAs/CCAs.	VGL	LR-VGL-022	Article 90	Article 85
	Grant access to Eudamed to CAs of third countries and International organisations for specific vigilance and post-market surveillance information	Enable granting access at the appropriate level to Eudamed for specific vigilance and post-market surveillance information to CAs of third countries and International organisations after agreement with the Commission..	VGL	LR-VGL-024	Article 92(4)	Article 87(4)

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CA of a third country or International organisation	View specific post-market surveillance and vigilance information available in Eudamed	Enable to access specific post-market surveillance and vigilance information available in Eudamed, in accordance with the access level granted to the CA of a third country or the International organisation	VGL	LR-VGL-025	Article 92(4)	Article 87(4)
Public	View vigilance and post-market surveillance information publically accessible	Enable the public (including healthcare professionals) to view with the appropriate level of access the vigilance and post-market surveillance information.	VGL	LR-VGL-027	Article 92(3)	Article 87(3)
	View FSNs	Enable the public to access the FSNs	VGL	LR-VGL-026	Article 89(8)	Article 84(8)

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7.6. Market Surveillance – MSU

Stakeholder	Stakeholder Task	Eudamed Requirement (Eudamed shall allow/enable)	Module	Requirement ID No	Legal Basis (MDR)	Legal Basis (IVDR)
Competent Authority	Provide an annual summary of the results of their surveillance activities	Enable entering an annual summary of the results of the surveillance activities	MSU	LR-MSU-001	Article 93(4) Article 100(1a)	Article 88(4) Article 95(1a)
		Make the annual summary of the results of the surveillance activities available to other CAs	MSU	LR-MSU-002	Article 93(4) Article 100(1a)	Article 88(4) Article 95(1a)
		Transmit immediately to all CAs concerned the annual summary of the results of the surveillance activities available	MSU	LR-MSU-014	Article 100(2)	Article 95(2)
	View all information on market surveillance in Eudamed	All the market surveillance information in Eudamed shall be accessible to the Member States and to the Commission	MSU	LR-MSU-024	Article 100(2)	Article 95(2)
	Enter final inspection reports	Enable entering a final inspection report following an inspection of an economic operator carried out for the purpose of market surveillance	MSU	LR-MSU-003	Article 93(7) Article 100(1b)	Article 88(7) Article 95(1b)
		Transmit immediately to all CAs concerned the final inspection report following an inspection of an economic operator carried out for the purpose of market surveillance	MSU	LR-MSU-015	Article 100(2)	Article 95(2)
	Enter summaries of the results of the reviews and assessment of the market surveillance activities of the MS	Enable entering at least every 4 years a summary of the results accessible to the public of the reviews and assessment of the market surveillance activities of the MS	MSU	LR-MSU-004	Article 93(8) Article 100(1f)	Article 88(8) Article 95(1f)
		Transmit immediately to all CAs concerned the summaries of the results accessible to the public of the reviews and assessment of the market surveillance activities of the MS	MSU	LR-MSU-016	Article 100(2)	Article 95(2)
	Communicate results of the review and assessment by the MS of the functioning of its market surveillance activities	Enable communication to the other MS and the COM the results of the review and assessment by the MS of the functioning of its market surveillance activities	MSU	LR-MSU-006	Article 93(8)	Article 88(8)

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	Notify devices presenting an unacceptable risk to health and safety	Enable notification to the COM, the other MS and the NB that issued a certificate for the device concerned of the results of an evaluation and the actions required to an economic operator for a device presenting an unacceptable risk to health and safety	MSU	LR-MSU-007	Article 95(2) Article 100(1c)	Article 90(2) Article 95(1c)
		Transmit immediately to all CAs concerned and the NBs concerned the results of an evaluation and the actions required to an economic operator for a device presenting an unacceptable risk to health and safety	MSU	LR-MSU-017	Article 100(2)	Article 95(2)
	Notify measures for devices presenting an unacceptable risk to health and safety	Enable notification to the COM, the other MS and the NB that issued a certificate for the device concerned of the measures taken by the MS where an economic operator does not take adequate corrective action within the allowed period for a device presenting an unacceptable risk to health and safety	MSU	LR-MSU-008	Article 95(4) Article 100(1c)	Article 90(4) Article 95(1c)
		Enable the notification to include all available details such as device identification and tracing, origin, nature and reasons for non-compliance, risks, nature and duration of the MS measures and arguments of the economic operator	MSU	LR-MSU-009	Article 95(5)	Article 90(5)
		Transmit immediately to all CAs concerned and the NBs concerned the measures taken by the MS where an economic operator does not take adequate corrective action within the required period for a device presenting an unacceptable risk to health and safety	MSU	LR-MSU-018	Article 100(2)	Article 95(2)
	Inform of any additional information relating to the non-compliance of the device presenting an unacceptable risk to health and safety	Enable a MS other than the MS initiating the procedure to inform the COM and the other MS of any additional relevant information relating to the non-compliance and of any measures it adopted for the device presenting an unacceptable risk to health and safety	MSU	LR-MSU-010	Article 95(6) Article 100(1c)	Article 90(6) Article 95(1c)

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		Transmit immediately to all CAs concerned any additional relevant information relating to the non-compliance and of any measures a MS adopted for the device presenting an unacceptable risk to health and safety	MSU	LR-MSU-019	Article 100(2)	Article 95(2)
	Inform on objections of the notified MS measures for a device presenting an unacceptable risk to health and safety	Enable a MS in the event of disagreement with the notified national measures for a device presenting an unacceptable risk to health and safety to inform the COM and the other MS of their objections	MSU	LR-MSU-011	Article 95(6) Article 100(1c)	Article 90(6) Article 95(1c)
		Transmit immediately to all CAs concerned objections to notified national measures for a device presenting an unacceptable risk to health and safety	MSU	LR-MSU-020	Article 100(2)	Article 95(2)
	Inform on measures taken for a non-compliant device not presenting an unacceptable risk to health or safety or to other aspects of the protection of public health	Enable a MS to inform the COM and the other MS on measures taken for a non-compliant device not presenting an unacceptable risk to health or safety or to other aspects of the protection of public health where the economic operator does not comply within the allowed period	MSU	LR-MSU-012	Article 97(2) Article 100(1d)	Article 92(2) Article 95(1d)
		Transmit immediately to all CAs concerned measures taken for a non-compliant device not presenting an unacceptable risk to health or safety or to other aspects of the protection of public health where the economic operator does not comply within the allowed period	MSU	LR-MSU-021	Article 100(2)	Article 95(2)
	Notify preventive health protection measures	Enable notification by a MS to the COM and all other MS on preventive health protection measures the MS has taken related to a device or a specific category or group of devices giving the reasons for its decision	MSU	LR-MSU-013	Article 98(2) Article 100(1e)	Article 93(2) Article 95(1e)
		Transmit immediately to all CAs concerned preventive health protection measures a MS has taken related to a device or a specific category or group of devices	MSU	LR-MSU-022	Article 100(2)	Article 95(2)
	Inform relevant NB and the DA on measures taken	Enable CA to inform the NB involved in the conformity assessment of the device concerned and the authority responsible for the NB (DA) of the	MSU	LR-MSU-025	Article 99(4)	Article 94(2)

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		measures taken for a device presenting an unacceptable risk to health and safety or for preventive health protection measures or for other non-compliance				
Commission	Set up, maintain and manage Eudamed	The Commission shall set up, maintain and manage the European database on medical devices ('Eudamed') for the following purposes: (e)to enable the competent authorities of the Member States and the Commission to carry out their tasks relating to this Regulation on a well-informed basis and to enhance the cooperation between them Eudamed shall include the following electronic systems: (g)the electronic system on market surveillance referred to in Article 100/95.	EUD	LR-NFS-002	Article 33(1, 2, 3, 8)	Article 30(1)
	Database controller	Information exchange between MS shall not be made public where to do so might impair market surveillance activities and co-operation between MS	MSU	LR-MSU-023	Article 100(3)	Article 95(3)
Notified Body	View, where applicable, information on market surveillance in Eudamed	Market surveillance information in Eudamed shall be accessible where applicable to the notified body that issued a certificate for the device concerned	MSU	LR-MSU-026	Article 100(2)	Article 95(2)
	Obtain immediately, where applicable, information on market surveillance in Eudamed	Transmit immediately information on market surveillance in Eudamed where applicable to the notified body that issued a certificate for the device concerned	MSU	LR-MSU-027	Article 100(2)	Article 95(2)
Public	View a summary of the results of the reviews and assessments of the market surveillance activities of a MS	Make accessible to the public summaries of the results of the reviews and assessments of the market surveillance activities of the MS	MSU	LR-MSU-005	Article 93(8) Article 100(1f)	Article 88(8) Article 95(1f)

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7.7. Horizontal Features

Stakeholder	Stakeholder Task	Eudamed Requirement (Eudamed shall allow/enable)	Module	Requirement ID No	Legal Basis (MDR)	Legal Basis (IVDR)
Competent Authority	View all information collated and processed by Eudamed	All the information collated and processed by Eudamed shall be accessible to the Member States and to the Commission.	EUD	LR-EUD-002	Article 33(5) Article 57(2)	Article 30(5) Article 52(2)
Commission	View all information collated and processed by Eudamed	All the information collated and processed by Eudamed shall be accessible to the Member States and to the Commission.	EUD	LR-EUD-002	Article 33(5) Article 57(2)	Article 30(5) Article 52(2)
	Set up, maintain and manage Eudamed	The Commission shall set up, maintain and manage the European database on medical devices ('Eudamed') for the following purposes: (a)to enable the public to be adequately informed about devices placed on the market, the corresponding certificates issued by notified bodies and about the relevant economic operators; (b)to enable unique identification of devices within the internal market and to facilitate their traceability; (c)to enable the public to be adequately informed about clinical investigations and to enable sponsors of clinical investigations to comply with obligations under Articles 62 to 80, Article 82, and any acts adopted pursuant to Article 81; (d)to enable manufacturers to comply with the information obligations laid down in Articles 87 to 90 or in any acts adopted pursuant to Article 91; (e)to enable the competent authorities of the Member States and the Commission to carry out	EUD	LR-NFS-002	Article 33(1, 2, 3, 8)	Article 30(1)

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	their tasks relating to this Regulation on a well-informed basis and to enhance the cooperation between them Eudamed shall include the following electronic systems: (a)the electronic system for registration of devices referred to in Article 29(4)/26(3); (b)the UDI-database referred to in Article 28/25; (c)the electronic system on registration of economic operators referred to in Article 30/27; (d)the electronic system on notified bodies and on certificates referred to in Article 57/52; (e)the electronic system on clinical investigations referred to in Article 73/69; (f)the electronic system on vigilance and post-market surveillance referred to in Article 92/87; (g)the electronic system on market surveillance referred to in Article 100/95. The Commission shall give due consideration to compatibility with national databases and national web-interfaces to allow for import and export of data. The Commission shall, by means of implementing acts, lay down the detailed arrangements necessary for the setting up and maintenance of Eudamed.				

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	Database controller	In relation to its responsibilities and the processing of personal data, the Commission shall be considered to be the controller of Eudamed and its electronic systems	EUD	LR-NFS-003	Article 33(9)	Article 30(1)
		Personal data shall be kept in a form which permits identification of data subjects for periods no longer than 10 years, or 15 years in case of implantable devices	EUD	LR-IAM-002	Article 33(6)	Article 30(1)
		Personal data may be processed only if the data subject has unambiguously given his or her consent	EUD	LR-IAM-003	[DPR] Article 5 (d)	[DPR] Article 5 (d)
		Where personal data are processed by automated means, measures shall be taken with the aim of ensuring that authorised users of a data-processing system can access no personal data other than those to which their access right refers	EUD	LR-IAM-004	[DPR] Article 22 §2 (e)	[DPR] Article 22 §2 (e)
		Where personal data are processed by automated means, measures shall be taken with the aim of preventing any unauthorised alteration or erasure of stored personal data	EUD	LR-IAM-008	[DPR] Article 22 §2 (c)	[DPR] Article 22 §2 (c)
		Where personal data are processed by automated means, measures shall be taken with the aim of preventing any unauthorised person from gaining access to computer systems processing personal data	EUD	LR-IAM-009	[DPR] Article 22 §2 (a)	[DPR] Article 22 §2 (a)
		Apply the terms of Regulation (EC) No 45/2001 to the processing of personal data (Personal Data Protection Regulation: [DPR]) This is a high level requirement: see specific requirement(s) LR-IAM-003, LR-IAM-004, LR-IAM-008, LR-IAM-009	EUD	LR-IAM-010	Article 110(2)	Article 103(2)
		Eudamed shall contain personal data only insofar as necessary to collate and process information in accordance with this Regulation	EUD	LR-IAM-011	Article 33(6)	Article 30(1)
Public	Search and view for information	Public parts of Eudamed are presented in a user-friendly and easily-searchable format.	EUD	LR-EUD-001	Article 33(5)	Article 30

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8. Functional Specification

8.1. Restricted site

8.1.1. Actor – ACT

Functional Specifications	#	Actors	Eudamed functional specification details (Eudamed shall allow/enable/transmit/assign/assist …)	Related requirements	Legal Priority	Timing Priority
FS-ACT-001 : Economic Operator and Sponsor registration	FS-ACT-001.01	EU MF, Non-EU MF, SPPP, AR, Importer, Sponsor	Enable Economic Operators (including system/procedure pack producer and manufacturer of class III implantable custom-made devices) and Sponsors to submit a registration request, get feedback on validation process and be registered after validation except for the Sponsors that do not need validation from Actor module (they will have to register but they will not need validation for submitting CIPS/PMCF/PMPF and adverse events)	LR-ACT-001 LR-ACT-002 LR-ACT-003	Required	High (1)
	FS-ACT-001.02	CA	Enable Competent Authorities to assess the registration requests of Economic Operators and to grant access to the first Local Actor Administrator user associated to the request	LR-ACT-005	Required	High (1)
	FS-ACT-001.03	EU MF, Non-EU MF, SPPP, AR, Importer, Sponsor	Assign (created by Eudamed) a Single Registration Number (SRN) to an Economic Operator whose registration request has been validated by a Competent Authority and an ID (created by Eudamed) to a Sponsor without validation	LR-ACT-005	Required	High (1)
	FS-ACT-001.04	EU, Non-EU MF, SPPP, AR, Importer, Sponsor, CA	Assist in detecting possible duplicate of Actors	LR-ACT-001 LR-ACT-005	Necessary	High (1)
	FS-ACT-001.05	AR	Enable an Authorised Representative designated by a non-EU Manufacturer to verify the registration request of this non-EU manufacturer	LR-ACT-005	Necessary	High (1)

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	FS-ACT-001.06	Non-EU MF	Enable a non-EU Manufacturer to designate an already registered Authorised Representative when applying for Registration	LR-ACT-001	Necessary	High (1)
FS-ACT-002 : Economic Operator and Sponsor details Update	FS-ACT-002.01	EU MF, Non-EU MF, SPPP, AR, Importer, Sponsor	Enable Economic Operators and Sponsors to update their details	LR-ACT-006 LR-ACT-007 LR-ACT-008	Required	High (1)
FS-ACT-003 : Search and view actor details	FS-ACT-003.01	EC, CA, NB, MF, SPPP, AR, Importer	List all Economic Operators and Sponsors whose registered actor details match a set of search criteria provided by the user	LR-ACT-010	Necessary	High (1)
	FS-ACT-003.02	EC, CA, NB, MF, SPPP, AR, Importer, Sponsor (only its own)	Display registered actor details (considering ownership, confidentiality and personal data protection) of an Economic Operator or Sponsor (a Sponsor may only see its own actor details)	LR-ACT-010 LR-UDID-005	Required	High (1)
	FS-ACT-003.03	EC, CA, NB, MF, SPPP, AR, Importer	Enable downloading in a file registered actor data of all Economic Operators and Sponsors whose details match a set of search criteria provided by the user	LR-ACT-016	Necessary	Medium (2)
FS-ACT-004 : Machine to machine (M2M) Actors data Download	FS-ACT-004.01	CA	Provide registered actor data of Economic Operators and Sponsors in Eudamed to MS national database	LR-ACT-016	Required	High (1)
FS-ACT-005 : Manage association (mandate) between non-EU manufacturer and AR	FS-ACT-005.01	Non-EU MF	Enable non-EU Manufacturers to enter Mandate information and to indicate whether the AR may or not submit incident reports and their corrective actions (Serious incident report, FSCA, FSN, PSR and Trend report) for devices covered by the mandate	LR-ACT-005 LR-UDID-001	Necessary	High (1)
	FS-ACT-005.02		Enable Manufacturers to Change Mandate scope and/or dates	LR-UDID-001	Necessary	High (1)
	FS-ACT-005.03	AR	Enable Authorised representatives to Accept/Reject Mandate to which they are associated	LR-UDID-001	Necessary	High (1)
	FS-ACT-005.04		Enable Authorised representatives to Accept/Reject an update in a mandate to which they are associated	LR-UDID-001	Necessary	High (1)
FS-ACT-006 : CA registration	FS-ACT-006.01	EC	Enable EC to enter CA data and CA Local Administrator	LR-NFS-002	Required	Medium(2)
FS-ACT-007 : Economic operators confirmation of	FS-ACT-007.01	EU MF, Non-EU MF, AR, Importer	Enable economic operators to confirm no later than 1 year after submission and every second year thereafter	LR-ACT-004 LR-ACT-011	Required	Medium (2)

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actor data accuracy			the accuracy of its actor data in Eudamed	LR-ACT-012		
FS-ACT-008 : Download/Upload for actor registration requests validation	FS-ACT-008.01	CA	Enable a CA to download in a file submitted actor registration requests this CA has to validate	LR-ACT-005	Necessary	High (1)
	FS-ACT-008.02	CA	Enable a CA to upload from a file validation outcomes for submitted actor registration requests this CA has to validate	LR-ACT-005	Necessary	High (1)
FS-ACT-009 : Search and view refused actor registration requests	FS-ACT-009.01	EC, CA	Enable EC and all CAs to search and view among all actor registration requests that have been refused by CAs	LR-ACT-005	Necessary	High (1)
FS-ACT-010 : Importer to associate itself to non-EU manufacturer (and their specific devices)	FS-ACT-010.01	Importer	Enable Importers to associate their details to manufacturers (and possibly their specific devices)	LR-ACT-017	Required	High (1)

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8.1.2. UDI/Device - UDID

Functional Specifications	#	Actors	Eudamed functional specification details (Eudamed shall allow/enable/transmit/assign/assist …)	Related requirements	Legal Priority	Timing Priority
FS-UDID-001 : Nomenclature data management	FS-UDID-001.01	EC	Provide in Eudamed an up-to-date list of medical devices nomenclature codes and their associated descriptions coming from the designated nomenclature provider (Article 26)	LR-UDID-002	Required	High (1)
FS-UDID-002 : UDI registration and update	FS-UDID-002.01	SPPP	Enable System/Procedure pack Producer to submit the required information on system or procedure pack Basic UDI-DI and UDI-DI	LR-UDID-007	Required	High (1)
	FS-UDID-002.02	SPPP	Enable System/Procedure pack Producer to update the allowed information for changes on system or procedure pack Basic UDI-DI and UDI-DI	-	Necessary	High (1)
	FS-UDID-002.04	EU MF, Non-EU MF, SPPP	Enable manufacturers and System/Procedure pack Producers to search and select among the list of medical device nomenclature codes and their description	LR-UDID-002	Required	High (1)
	FS-UDID-002.05	EU MF, Non-EU MF	Enable manufacturers to enter and to submit the required information on device Basic UDI-DI and UDI-DI	LR-UDID-001 LR-UDID-011	Required	High (1)
	FS-UDID-002.06		Enable manufacturers to update the allowed information for changes on device Basic UDI-DI and UDI-DI	-	Necessary	High (1)
	FS-UDID-002.08		Prevent manufacturers to enter several times the same UDI-DI and guarantee unicity of Basic UDI-DI for a UDI-DI (one and only one Basic UDI-DI can be associated to a UDI-DI)	LR-NFS-002	Required	High (1)
	FS-UDID-002.09		Enable manufacturers to add new device UDI-DI for the same Basic UDI-DI and to update device UDI data to keep the information up-to-date	LR-UDID-001	Required	High (1)

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FS-UDID-003 : Device registration and update	FS-UDID-003.01	EU MF, Non-EU MF	Enable manufacturers to submit the required information on device (not the one to be entered only by NB (SS(C)IP))	LR-UDID-003	Required	High (1)
	FS-UDID-003.02		Enable manufacturers to update device data to keep the information up-to-date (except SS(C)P)	LR-UDID-004	Required	High (1)
FS-UDID-004 : Indicate disagreement for a Basic UDI-DI and related UDI-DI and device information	FS-UDID-004.01	AR	Enable an Authorised Representative to indicate its disagreement with information related to a Basic UDI-DI referencing its AR and related UDI-DI and device information and to provide the reasons	LR-UDID-013	Necessary	Medium (2)
FS-UDID-005: Confirm device data with related Certificate data	FS-UDID-005.01	Notified Body (NB)	Enable to confirm the information on device data and related certificate ID where applicable if not already done	LR-UDID-006	Required	High (1)
FS-UDID-006 : Search, view and download UDI-DI and Device data (including SS(C)P)	FS-UDID-006.01	EC, CA, NB, MF, SPPP, AR, Importer	List devices with their UDI-DIs whose (Basic) UDI-DI and Device data match a set of search criteria provided by the user	LR-UDID-010 LR-UDID-013	Necessary	High (1)
	FS-UDID-006.02	EC, CA, NB, MF, SPPP, AR, Importer	Display (Basic) UDI-DI data and Device data of a Device associated to a Basic UDI-DI	LR-UDID-010 LR-UDID-013	Required	High (1)
FS-UDID-007 : Search and view device nomenclature data	FS-UDID-007.01	EC, CA, NB, MF, SPPP, AR, Importer	Enable to view and search among the list of medical device nomenclature codes and their description	LR-UDID-002	Necessary	High (1)
FS-UDID-008 : (M2M) Upload and Download of Basic UDI-DI, UDI-DI and device data	FS-UDID-008.01	EU MF, Non-EU MF	Enable manufacturers to submit through upload (M2M or XML file) the required information (new and update) on Basic UDI-DI, UDI-DI and device data (with bulk upload providing multiple records possibility).	LR-DTX-001 LR-UDID-011	Required	High (1)
	FS-UDID-008.02	SPPP	Enable System/Procedure pack Producer to submit through upload (M2M or XML file) the required information on (new and update) on Basic UDI-DI and UDI-DI	LR-DTX-007	Necessary	High (1)
	FS-UDID-008.03	EC, CA, NB, MF, SPPP, AR, Importer	Enable downloading (M2M) the registered (Basic) UDI-DI data and Device data or to extract in an electronic format a search result list	LR-NFS-002 LR-DTX-002 LR-DTX-003 LR-DTX-004 LR-DTX-005 LR-DTX-006	Required	High (1)

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FS-UDID-009 : SS(C)P upload in device data	FS-UDID-009.01	NB	Enable the Notified Body to upload the summary of safety (and clinical) performance (SS(C)P) and enter related meta-data to device data already provided by a manufacturer	LR-CRF-021	Required	High (1)
FS-UDID-010 : Enable linking between Basic UDI-DI	FS-UDID-010.01	EU MF, Non-EU MF	Enable manufacturers to link one of its Basic UDI-DI to another one and to give a reason	LR-UDID-001	Necessary	Low (3)

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8.1.3. Certificate & Notified Body – CRF

Functional Specifications	#	Actors	Eudamed functional specification details (Eudamed shall allow/enable/transmit/assign/assist …)	Related requirements	Legal Priority	Timing Priority
FS-CRF-003 : Manage list of nominated experts	FS-CRF-003.01	EC	Enable managing a list of nominated experts with information on their specific field of competence and expertise.	LR-CRF-008	Required	High (1)
FS-CRF-002 : View list of nominated experts	FS-CRF-002.01	EC, CA (including DA)	Allow viewing a list of nominated experts for joint assessment together with information on their specific field of competence and expertise.	LR-NFS-002 LR-CRF-007 LR-CRF-008	Required	High (1)
FS-CRF-011 : Provide NB actor and designation data	FS-CRF-011.01	EC	Keep up-to-date in Eudamed from Nando information relating to the NB Actor and the notification of the NB, along with the accompanying and objection/opinion/responses docs (if applicable) related to the notification procedure.	LR-CRF-011	Required	High (1)
FS-CRF-013 : View information related to NB	FS-CRF-013.01	EC, CA (including DA), NB, MF, SPPP, AR, Importer	Enable to view NB information relating to its Actor information, notifications for MDR/IVDR Information and list of subsidiaries.	LR-NFS-002 LR-CRF-026	Required	High (1)
	FS-CRF-013.02	EC, CA (including DA)	For each MDR/IVDR notification of a NB, enable to view the accompanying and objection/opinion/responses docs (if applicable) related to the notification procedure.	LR-NFS-002 LR-CRF-007	Required	High (1)
	FS-CRF-013.03	EC, CA (including DA), NB, MF, SPPP, AR, Importer	Enable to view the list of NBs	LR-NFS-002 LR-CRF-026	Required	High (1)
FS-CRF-004 : Manage MS Summary Report	FS-CRF-004.01	DA	Enable to manage/upload own MS Summary Reports on monitoring and on-site assessment activities regarding the NBs.	LR-CRF-014	Required	Medium (2)
FS-CRF-001 : View MS Summary Report on monitoring and on-site assessment activities regarding NBs	FS-CRF-001.01	EC, CA (including DA), NB, MF, SPPP, AR, Importer	Enable to select and view for a specific MS, one of its annual Summary Reports on monitoring and on-site assessment activities regarding NBs and their subsidiaries.	LR-NFS-002 LR-CRF-014	Required	Medium (2)
FS-CRF-009 : Notification of refusal or withdrawal of applications for conformity assessment	FS-CRF-009.01	NB	Enable the NB to enter notifications for refusal of applications for conformity assessment or withdrawal by the MF before NB decision on the conformity assessment.	LR-CRF-006 LR-CRF-015 LR-NFS-002	Required	High (1)

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FS-CRF-010 : Search and view notifications of refusal or withdrawal of applications for conformity assessment	FS-CRF-010.01	EC, CA (including DA), NB	Enable search and view information about refused/withdrawn applications for conformity assessment.	LR-NFS-002	Required	High (1)
FS-CRF-021: Manage list of expert panels	FS-CRF-021.01	EC	Enable to manage the list of expert panels for CECP	LR-CRF-024	Necessary	Medium (2)
FS-CRF-022: View list of expert panels	FS-CRF-022.01	EC, CA (including DA), NB	Enable to view the list of expert panels for CECP	LR-CRF-024	Necessary	Medium (2)
FS-CRF-012 : Manage list of subsidiaries	FS-CRF-012.01	NB	Enable NB to manage its list of subsidiaries.	LR-CRF-001	Required	High (1)
FS-CRF-018 : Grant access to the first Local NB Actor Administrator	FS-CRF-018.01	Authority Responsible for NBs (DA)	Enable the designating authority of a NB to validate the access requests of the first Local NB Actor Administrator	LR-NFS-002 LR-NFS-003	Necessary	Medium (2)
FS-CRF-014 : Clinical evaluation consultation procedure (CECP) for class III implantable and class IIb active devices intended to administer a medicinal product* * To be referred to as 'CECP devices'	FS-CRF-014.01	NB	Enable to notify (the EC, CAs and the Authority Responsible for the NBs) CECP devices and to provide their clinical evaluation assessment (report) and whether a CECP is to be applied to them or not.	LR-CRF-002	Required	High (1)
	FS-CRF-014.02	NB	In addition to the FS-CRF-014.01, enable providing (to the EC) the MF's clinical evaluation documentation (clinical evaluation report, clinical evaluation plan, PMCF plan, PMCF evaluation report, etc.) for CECP devices subject to the CECP.	LR-CRF-009	Required	High (1)
	FS-CRF-014.03	EC	Enable to assign users associated to an expert panel to a CECP dossier.	LR-CRF-012	Nice to have	High (1)

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	FS-CRF-014.04	EC/Expert Panel chair user	Enable the expert panel chair to notify the COM and NB whether or not the panel will provide an opinion for the assigned case	LR-CRF-013	Required	High (1)
	FS-CRF-014.05	EC/Expert Panel chair user	Enable to enter and to submit the expert panel reasons for not providing a Scientific Opinion for assigned CECP devices.	LR-CRF-020	Necessary	High (1)
	FS-CRF-014.06	EC/Expert Panel chair user	Enable to enter and to submit to the NB the expert panel Scientific Opinion for assigned CECP devices.	LR-CRF-017	Necessary	High (1)
	FS-CRF-014.07	NB	Enable to enter and to submit to the EC the justification for not following in its conformity assessment report the expert panel advice	LR-CRF-027	Necessary	High (1)
FS-CRF-015 : Workflow control for CECP	FS-CRF-015.01	EC	The system shall be able to inform/alert users that a new task has arrived or the legal deadline (set by the regulation) for a task is coming, in part concerning the following tasks: • For EC users to assign an Expert Panel to a CECP; • For Expert Panel to notify decision to provide Scientific Opinion or not; • For EC/Expert Panel users to notify reasons for not providing Scientific Opinion; • For EC/Expert Panel users to provide Scientific Opinion. For the calculation of the legal deadlines the requirements of Regulation No 1182/71 of the Council of 3 June 1971 shall be taken in account.	-	Nice to have	Medium (2)
FS-CRF-016 : Search and view information on CECP	FS-CRF-016.01	EC (including expert panel users having been assigned to the CECP), NB, CA (including DA)	Enable to view a list of CECPs and corresponding devices whose data match a set of search criteria provided by the user.	LR-NFS-002	Required	High (1)

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FS-CRF-005 : Issued certificates registration	FS-CRF-005.01	NB	Enable to register information about certificates NB has issued, in accordance with the minimum content of certificates defined in Annex XII [MDR and IVDR] (but not all has to be as meta-data in Eudamed). Enable to notify CAs (with DAs) for scrutiny mechanism about certificates granted to devices for which a clinical evaluation consultation procedure (CECP) has been performed / to class D devices and provide the required information.	LR-CRF-003 LR-CRF-019 LR-CRF-010	Required	High (1)
FS-CRF-006 : Registration of new certificate version	FS-CRF-006.01	NB	Enable NB to register new certificate versions it has issued, due to amendment, supplement, suspension, reinstatement, restriction, renewal or withdrawal.	LR-CRF-003	Required	High (1)
FS-CRF-007 : Registration of refused certificates	FS-CRF-007.01	NB	Enable NB to register information about refused certificates.	LR-CRF-003	Required	High (1)
FS-CRF-008 : Search and view certificates and refused certificates	FS-CRF-008.01	EC, CA (including DA), NB, MF, SPPP, AR, Importer	Enable search and view information about issued/refused certificates and updates to issued certificates.	LR-NFS-002	Required	High (1)
FS-CRF-017 : Requested withdrawal/suspension of certificates	FS-CRF-017.01	Authority Responsible for NBs (DA)	Enable to view and manage information on certificates for which the DA has required the suspension or withdrawal.	LR-CRF-023	Required	High (1)
	FS-CRF-017.02	Authority Responsible for NBs (DA)	Enable to make accessible and to inform by email the EC and the CAs where the manufacturer is established about certificates for which the DA has required the suspension or withdrawal.	LR-CRF-025	Required	High (1)

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	FS-CRF-017.03	EC, CA (including DA)	Enable to see certificates for which a DA has requested the suspension or withdrawal.	LR-CRF-025 LR-NFS-002	Required	High (1)
FS-CRF-019 : Machine to machine (M2M) Certificate information upload	FS-CRF-019.01	NB	Import using a M2M web service certificates NB own information from their database to Eudamed for submission of issued, updates, renewal and refused certificates	-	Necessary	High (1)
FS-CRF-020 : Machine to machine (M2M) conformity and certificate information download	FS-CRF-020.01	NB	Export using a M2M web service NB own information submitted for a certificate by that NB in Eudamed to that NB database.)	LR-CRF-016	Nice to have	Medium (2)
	FS-CRF-020.02	CA (including DA)	Export using a M2M web service information submitted for a conformity assessment or a certificate by NB together with related information in Eudamed to the national MS database of that CA	LR-CRF-016 LR-NFS-002	Necessary	High (1)

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8.1.4. Clinical Investigation - CIPS

Functional Specifications	#	Actors	Eudamed functional specification details (Eudamed shall allow/enable/transmit/assign/assist …)	Related requirements	Legal Priority	Timing Priority
FS-CIPS-015: Manage list of Ethics Committees	FS-CIPS-015.01	Competent Authority (CA)	Enable Competent Authority responsible for CI/PS of a Member State to manage the list of Ethics Committees of its Member States	-	Necessary	Medium (2)
FS-CIPS-001 : Manage application/notification for CI/PS	FS-CIPS-001.01	Sponsor	Enable the sponsor to enter and submit an application to the MS(s) where the CI/PS will be conducted together with all relevant data and documentation as per the requirements of Chapter II of Annex XV of MDR / Section 2 and 3 of Annex XIII and in Annex XIV of IVDR. Generate a Union-wide unique single identification number (CI/PS SIN) for the CI/PS directly after the first save (before submission).	LR-CIPS-001 LR-CIPS-010	Required	Medium (2)
	FS-CIPS-001.02		Enable the sponsor to enter and submit an application for CI/PS, to assess outside the scope of its intended purpose, a device which already bears the CE marking, to the MS(s) where the CI/PS will be conducted, together with all relevant data and documentation as per the requirements of Chapter II of Annex XV of MDR / Section 2 and 3 of Annex XIII and in Annex XIV of IVDR. Generate a Union-wide unique single identification number (CI/PS SIN) for the CI/PS directly after the first save (before submission).	LR-CIPS-009 LR-CIPS-010	Required	Medium (2)
	FS-CIPS-001.03		Enable the sponsor to enter and submit a single application for CI/PS to be conducted in more than one MS that, upon receipt, is transmitted electronically to all MSs in which the CI/PS is to be conducted. Enable the sponsor to propose the Coordinating MS (CMS) among the MSs in which the CI/PS is to be conducted. Generate a Union-wide unique single identification number (CI/PS SIN) for the CI/PS directly after the first save (before submission).	LR-CIPS-012 LR-CIPS-002 LR-CIPS-010	Required	Medium (2)

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	FS-CIPS-001.04		Enable the sponsor to update the relevant data due to any change occurring to the application data and documentation referred to in Chapter II of Annex XV of MDR / Chapter I of Annex XIV of IVDR and make that change clearly identifiable. Enable the sponsor to indicate if an update or a correction. The MSC(s) shall be notified of the update or correction.	LR-CIPS-005	Required	Medium (2)
	FS-CIPS-001.05		Enable the sponsor to provide additional information requested by the (C)MS within the time set by the MSC during the period when the application is being assessed. The (C)MS shall be notified when additional information is provided.	LR-CIPS-007	Necessary	Medium (2)
	FS-CIPS-001.06		Enable the sponsor to comment or complete, within the time limit set by the MS, a submitted application for CI/PS after the MS has informed the sponsor and indicated that the CI/PS applied for does not fall within the scope of this Regulation or that the application dossier is not complete. The MSC(s) shall be notified of the update.	LR-CIPS-006	Required	Medium (2)
	FS-CIPS-001.07		Enable the sponsor to enter and notify a PMCF/PMPF investigation/study to the MSC(s) with all the required data and documentation referred to in Chapter II of Annex XV of MDR / Section 2 of Part A of Annex XIII and in Annex XIV of IVDR. Generate a Union-wide unique single identification number (CI/PS SIN) for the PMCF/PMPF directly after the first save (before submission).	LR-CIPS-003 LR-CIPS-010	Required	Medium (2)
FS-CIPS-002 : Withdraw application or notification for CI/PS or PMCF/PMPF	FS-CIPS-002.01	Sponsor	Enable the sponsor to indicate that an application or notification for CI/PS or PMCF/PMPF is withdrawn by that sponsor prior to a decision by a MS or to the start of the CI/PS or PMCF/PMPF. The MSC(s) shall be notified of the withdrawn.	LR-CIPS-008	Required	Medium (2)
FS-CIPS-003 : Manage validation of application for CI/PS and setting of validation date	FS-CIPS-003.01	Competent Authority of the Coordinating MS (CMS)	In case of single application of CI/PS for more than one MS, enable the CMS to enter/confirm and notify the sponsor, within 6 days of receipt of the single application, that it is the CMS for this single application for CI/PS.	LR-CIPS-043	Necessary	Medium (2)

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			Enable the Notification date to be set at the date on which the notification is submitted or at the end of the 6 days of receipt.			
	FS-CIPS-003.02		In case of single application of CI/PS for more than one MS, enable the CMS, within 10 days of the notification date, to enter its validation decision as to whether the CI/PS falls within the scope of MDR/IVDR and as to whether the application is complete and to notify the sponsor of its decision. The completeness of the documentation referred to in Sections 1.13, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XV shall be assessed separately by each CA of the MSC(s). General provisions for validation by a CA shall apply to the CA of the CMS (see functional specifications below).	LR-CIPS-026	Necessary	Medium (2)
	FS-CIPS-003.08	Competent Authority (CA)	In case of single application of CI/PS for more than one MS, enable each MS attached to the single application to indicate, within 6 days of receipt of the single application, which MS attached to the single application should be the CMS if not the one selected by the sponsor. In case of no agreement of the MS on a CMS, the CMS proposed by the sponsor shall assume that role.	LR-CIPS-043	Necessary	Medium (2)
	FS-CIPS-003.04		Enable the CA of a MSC to submit within 7 days of the notification date any considerations for the purpose of validation of a CI/PS application following the coordinated assessment procedure	LR-CIPS-044	Necessary	Medium (2)
	FS-CIPS-003.05		Enable the CA to provide its decision on the validation of an application and to notify the sponsor that the CI/PS falls within the scope of MDR/IVDR and the application dossier is complete in accordance with Chapter II of Annex XV of MDR / Chapter I of Annex XIV of IVDR. Enable the CA to extend the time limit for its validation decision by a further of 5 days (beyond the initial max of	LR-CIPS-026 LR-CIPS-025	Necessary	Medium (2)

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			10 days) before the current time limit expires. Validation date is set from the date of notification to the sponsor by the CA/Eudamed or if there is no decision/notification from the CA, the validation date shall be set (by CA/Eudamed?) as the last day when the current time limit for the CA expires.			
	FS-CIPS-003.06		In case the CA decision is that the application does not fall within the scope of MDR/IVDR or is not complete, enable the CA to set a time limit (max 10 days) and inform the sponsor of this time limit together with its negative decision for comment or to complete the application by the sponsor with a justification. Enable the CA to extend this time limit for the sponsor of a maximum of 20 (beyond the initial max of 10 days) before the current time limit expires. Enable the CA to extend the time limit for its validation decision by a further of 5 days (beyond the initial max of 10 days) before the current time limit for the CA expires.	LR-CIPS-027 LR-CIPS-028 LR-CIPS-025	Necessary	Medium (2)
	FS-CIPS-003.07		Enable the CA to provide its decision on the validation of a CI/PS after a previous negative decision and to notify the sponsor, within 5 days of receipt of the comments or additional information from the sponsor, whether the CI/PS is considered as falling within the scope of MDR/IVDR and the application is complete. Enable the CA to extend the time limit for its validation decision by a further of 5 days (beyond the initial max of 5 days) before the current time limit expires. Validation date is set from the date of notification to the sponsor by the CA/Eudamed or if there is no decision/notification from the CA, the validation date shall be set (by CA/Eudamed?) as the last day when the current time limit for the CA expires.	LR-CIPS-029 LR-CIPS-025	Necessary	Medium (2)

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FS-CIPS-004 : Manage authorisation of CI/PS and setting of time limit for authorisation	FS-CIPS-004.01	Competent Authority	Enable the CA to provide its decision for the authorisation of a CI/PS and to notify the sponsor of its authorisation decision. Enable the CA (or Eudamed) to set the time limit for the CA to notify the sponsor of its authorisation (within 45 days of the validation date).	LR-CIPS-031	Necessary	Medium (2)
	FS-CIPS-004.02		Enable the CA to request additional information from the sponsor during the period when the application is being assessed within the time limit for providing its authorisation. (Enable the CA to set a time limit for the sponsor to provide the additional information)	LR-CIPS-030	Necessary	Medium (2)
	FS-CIPS-004.03		Enable the CA to suspend the period for providing its authorisation because it has requested additional information by providing the date from which it has requested the additional information and the date when it has received the additional information from the sponsor.	LR-CIPS-030	Necessary	Medium (2)
	FS-CIPS-004.04		Enable the CA to extend the period of 45 days for notification of the authorisation by updating the time limit for the authorisation already set by a further maximum 20 days (65 days within validation date without considering possible suspension for additional information request) with its justification, or by a further 50 days (95 days within validation date without considering possible suspension for additional information request) if by CMS for class IIb/C and class III/D device and to inform the sponsor of that extension.	LR-CIPS-032	Necessary	Medium (2)
FS-CIPS-005 : Enter and communicate the start of the CI/PS or re-start after a suspension or temporary halt or start with substantial modifications	FS-CIPS-005.01	Sponsor	Enable the sponsor to enter and communicate to the MSC (and CMS) the start date of a CI/PS or its re-start date after a suspension or temporary halt or its start date with substantial modifications	-	Necessary	Medium (2)

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FS-CIPS-006 : Manage substantial modifications to CI/PS after authorisation or PMCF/PMPF	FS-CIPS-006.01	Sponsor	Enable the sponsor to enter and notify substantial modifications to an authorised CI/PS or PMCF/PMPF to the MS(s) in which the CI/PS or PMCF/PMPF is being or is to be conducted (all MSC(s)) of the reasons for and the nature of those modifications with the updated data and documentation in a new version of the required data and documentation referred in Chapter II of Annex XV of MDR / in Annex XIV of IVDR. Changes shall be clearly identifiable between former and new version.	LR-CIPS-004	Required	Medium (2)
FS-CIPS-007 : Manage authorisation for substantial modifications to CI/PS or PMCF/PMPF	FS-CIPS-007.01	Competent Authority	Enable the CA to enter, and notify to the sponsor within 38 days of the notification of the sponsor, its authorisation or refusal for substantial modifications to an authorised/started CI/PS or PMCF/PMPF with its justification and/or the negative opinion by an Ethic Committee	LR-CIPS-036	Necessary	Medium (2)
	FS-CIPS-007.02		Enable the CA to enter, and notify to the sponsor, the number of days (max 7) until which the notification for possible refusal (or authorisation) is extended	LR-CIPS-037	Necessary	Medium (2)
	FS-CIPS-007.03		Enable the CA to correct any justification and to notify the sponsor and MS concerned.	-	Necessary	Medium (2)
FS-CIPS-008 : Manage recording and reporting of adverse events that occur during CI/PS	FS-CIPS-008.01	Sponsor	Enable the sponsor to enter and report without delay to all MSC(s) any serious adverse event or any device deficiency that might have led to a serious adverse event that occurs during CI/PS, also those that occurred in third countries in which a CI/PS is performed under the same CI/PS plan as one applying to a CI/PS covered by MDR/IVDR. As of 26 May 2020, enable to report serious adverse event or any device deficiency that occurs in CI that have started prior to 26 May 2020 to be conducted in accordance with MD Directives. Enable reporting of serious adverse event or device deficiency that occurs during PMCF investigation / PMPF	LR-CIPS-023	Required	Medium (2)

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			study (vigilance provisions applies, incident report instead (see FS-VGL-004)). To ensure timely reporting, enable submission of an initial report that is incomplete followed up by a complete report. Upon receipt, transmit electronically the new report to all MSC(s).			
	FS-CIPS-008.02		Enable the sponsor to update or correct and report without delay to all MSC(s) any change or correction on their already reported complete SAE or device deficiency report	-	Necessary	Medium (2)
	FS-CIPS-008.03		Enable the sponsor to enter and report without delay to all MSC(s) any new findings/updates making a new version on already reported serious adverse event or device deficiency that occurs during CI/PS, also those that occurred in third countries in which a CI/PS is performed under the same CI/PS plan as one applying to a CI/PS covered by MDR/IVDR. As of 26 May 2020, enable to report any new findings/updates on already reported serious adverse event or device deficiency that occurs in CI that have started prior to 26 May 2020 to be conducted in accordance with MD Directives. Upon receipt, transmit electronically the new findings/updates to all MSC(s).	LR-CIPS-024	Required	Medium (2)
FS-CIPS-009 : Manage information at the end of a CI/PS or PMCF/PMPF or in the event of a temporary halt or early termination	FS-CIPS-009.01	Sponsor	Enable the sponsor to indicate that a CI/PS or PMCF/PMPF has been temporarily halted or terminated early, providing a justification, and to inform by email the MS(s) in which that CI/PS or PMCF/PMPF (MSC(s)) PS has been temporarily halted or terminated early.	LR-CIPS-018	Necessary	Medium (2)
	FS-CIPS-009.02		Enable the sponsor to provide the date of the end of a CI/PS or PMCF/PMPF and to notify each/all MS(s) in which	LR-CIPS-020	Necessary	Medium (2)

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			a CI/PS or PMCF/PMPF was being conducted of the end of that CI/PS or PMCF/PMPF in that MS (MSC(s)). That notification shall be made within 15 days of the end of the CI/PS.			
	FS-CIPS-009.03		Enable the sponsor to enter/upload and submit to the MSC(s) both the CI/PS or PMCF/PMPF outcome report as referred in Section 2.8 of Chapter I and Section 7 of Chapter III of Annex XV of MDR / Section 2.3.3 of Part A of Annex XIII of IVDR and the summary irrespectively of the outcome (end, early termination or temporary halt) within one year of the end or within 3 months of the early termination or temporary halt.	LR-CIPS-022	Required	Medium (2)
	FS-CIPS-009.04		Enable the sponsor to inform for later date of submission of CI/PS or PMCF/PMPF report with justifications, due to scientific reasons, as well as specify the date of provision of the report and summary and justification for the delay in CI/PS or PMCF/PMPF plan and to update accordingly the CI/PS or PMCF/PMPF plan document stored in Eudamed.	LR-CIPS-022	Necessary	Medium (2)
	FS-CIPS-009.05		Enable the sponsor to update or correct, and inform without delay all MSC(s) of any change or correction on, their already submitted outcome report and/or summary	-	Necessary	Medium (2)
FS-CIPS-010 : Manage coordinated assessment procedure for CI/PS	FS-CIPS-010.01	Competent Authority of the Coordinating MS (CMS)	Enable the CA of the CMS of a CI/PS following the coordinated assessment procedure to transmit its draft assessment report within 26 days of the validation date, to the other MSCs	LR-CIPS-045	Necessary	Medium (2)
	FS-CIPS-010.02		Enable the CA of the CMS of a single application for CI/PS to enter and transmit its final assessment report, taking due account of comments an proposals received from MSCs, within 45 days of the validation date, to the sponsor and the other MSCs. Set final assessment report transmission date.	LR-CIPS-048	Necessary	Medium (2)
	FS-CIPS-010.03		Enable the CA of the CMS to enter and to notify the sponsor, within five days of the final assessment report transmission date by the CA of the CMS, in one single	LR-CIPS-031	Required	Medium (2)

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			decision whether the CI/PS is authorised, whether it is authorised subjects to conditions (to provide) or whether authorisation has been refused by each CA concerned in the single application for CI/PS.			
	FS-CIPS-003.03	Competent Authority	Enable a CA responsible for CI/PS to specify whether they are ready to participate to coordinated procedures for any future application of CI/PS taking place in their Member State and to be coordinating CA or not with the possibility to specify the period in which it will be applicable. It will allow a sponsor to select a coordinating CA that will always be ready to do it for a single application and to have always and only Member States ready to be part of a single application with coordinated procedure. After 26 May 2027 for MDR, 2029 for IVDR, all MS shall be required to apply that procedure.	LR-CIPS-033	Necessary	Medium (2)
	FS-CIPS-010.04		Enable the CA of a MSC to transmit to the CMS within 38 days of the validation date any comments and proposals on the draft assessment report transmitted by the CMS of a CI/PS following the coordinated assessment procedure and the underlying application	LR-CIPS-047	Necessary	Medium (2)
	FS-CIPS-010.05		Enable the CA to enter and to communicate its disagreement on the conclusion of the CMS concerning the area of coordinated assessment, together with a detailed justification, to the Commission, to all other MSCs and to the sponsor, Prevent disagreement where the conclusion of the CMS is that the CI/PS is not acceptable concerning the area of coordinated assessment (shall be deemed to be the conclusion of all MSCs). The area of coordinated assessment is on the grounds described in Article 78(8) MDR / 74(8) IVDR.	LR-CIPS-046	Required	Medium (2)
FS-CIPS-011 : Manage exchange of information and communication to all MS	FS-CIPS-011.01	Competent Authority	Enable the CA to notify the sponsor for a revoke of authorisation of a CI/PS, or for a suspension or termination of a CI/PS with its justification	-	Necessary	Medium (2)

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and the Commission on decisions and the grounds therefor related to CI/PS	FS-CIPS-011.02		Enable the CA to provide required modifications to an authorised/started CI/PS of a sponsor and to notify this sponsor	-	Necessary	Medium (2)
	FS-CIPS-011.03		Enable the CA to notify the sponsor of an end of suspension of a CI/PS with its justification and possible conditions	-	Necessary	Medium (2)
	FS-CIPS-011.04		Enable the CA to update or correct justifications and/or conditions, and inform without delay the sponsor and all MSC(s) of any change or correction on, their already submitted measures	-	Necessary	Medium (2)
	FS-CIPS-011.05		Enable the CA to provide and to communicate to all MS and the Commission the following measures taken on its territory with its justification and possible opinions from the sponsor and/or the investigator: - Revoke of authorisation for CI/PS; - Suspend or terminate CI/PS; - Require modifications from the sponsor for any aspect of CI/PS.	LR-CIPS-039	Required	Medium (2)
	FS-CIPS-011.06		Enable the CA to communicate to all MS and the Commission CI/PS that it refused with its justification	LR-CIPS-039	Required	Medium (2)
	FS-CIPS-011.07		Communicate to all MS and the Commission that the CA has been notified by the sponsor of the early termination of CI/PS on safety grounds	LR-CIPS-039	Required	Medium (2)
	FS-CIPS-011.08		Communicate to all MS and the Commission that an application is withdrawn by the sponsor prior to a decision by a MS	LR-CIPS-008 LR-CIPS-039	Required	Medium (2)
FS-CIPS-012 : Search and view information on CI/PS	FS-CIPS-012.01	Sponsor	Search among list of CI/PS entered by that sponsor	LR-CIPS-001 LR-CIPS-009 LR-CIPS-012 LR-CIPS-003	Necessary	Medium (2)
	FS-CIPS-012.02		Display information details of a CI/PS entered by that sponsor	LR-CIPS-001 LR-CIPS-009 LR-CIPS-012 LR-CIPS-003	Necessary	Medium (2)
	FS-CIPS-012.03		Download/Extract in a file outside Eudamed information details of a CI/PS displayed in Eudamed	-	Nice to have	Low (3)

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	FS-CIPS-012.04		Search among list of recorded and reported adverse events that occurred during CI/PS entered by that sponsor	LR-CIPS-023 LR-CIPS-024	Necessary	Medium (2)
	FS-CIPS-012.05		Display information details of a recorded and/or reported adverse events that occurred during CI/PS entered by that sponsor	LR-CIPS-023 LR-CIPS-024	Necessary	Medium (2)
	FS-CIPS-012.06		Download/Extract in a file outside Eudamed information details of an adverse event displayed in Eudamed	-	Nice to have	Low (3)
	FS-CIPS-012.07		Search among list of CI/PS outcome reports and summaries entered by that sponsor	LR-CIPS-022	Necessary	Medium (2)
	FS-CIPS-012.08		Display information details of a CI/PS outcome report and summary entered/uploaded by that sponsor	LR-CIPS-022	Necessary	Medium (2)
	FS-CIPS-012.09		Download/Extract in a file outside Eudamed outcome report and summary displayed in Eudamed	-	Nice to have	Low (3)
	FS-CIPS-012.10	Competent Authority, Commission	Search among list of all submitted CI/PS from a list of search criteria on CI/PS data attributes (withdrawn, refused, early termination and/or temporary halt included)	LR- MDR -002 LR-CIPS-035	Necessary	Medium (2)
	FS-CIPS-012.11		Display information details of any submitted CI/PS (withdrawn, refused, early termination and/or temporary halt included, with final assessment report by CMS and possible disagreement by CA for a single application)	LR- MDR -002 LR-CIPS-035	Necessary	Medium (2)
	FS-CIPS-012.12		Download/Extract in a file outside Eudamed information details of a CI/PS displayed in Eudamed	-	Nice to have	Low (3)
	FS-CIPS-012.13		Search among list of all reported adverse events from a list of search criteria on adverse event/device deficiency data attributes	LR- MDR -002 LR-CIPS-035	Necessary	Medium (2)
	FS-CIPS-012.14		Display information details of any reported adverse event or device deficiency	LR- MDR -002 LR-CIPS-035	Necessary	Medium (2)
	FS-CIPS-012.15		Download/Extract in a file outside Eudamed information details of an adverse event displayed in Eudamed	-	Nice to have	Low (3)
	FS-CIPS-012.16		Search among list of all CI/PS outcome reports and summaries from a list of search criteria on CI/PS outcome final report meta-data attributes	LR-CIPS-035	Necessary	Medium (2)
	FS-CIPS-012.17		Display information details of any CI/PS outcome report or summary	LR-CIPS-035	Necessary	Medium (2)

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	FS-CIPS-012.18		Download/Extract in a file outside Eudamed outcome report and summary displayed in Eudamed	-	Nice to have	Low (3)
	FS-CIPS-012.19		Search among list of all submitted measures taken (Revoke of authorisation, Suspension or termination, Required modifications) by CA from a list of search criteria on measure data attributes	LR-CIPS-035	Necessary	Medium (2)
	FS-CIPS-012.20		Display information details of any submitted measure taken by a CA with its justification and possible opinion from the sponsor and/or the investigator	LR-CIPS-035	Necessary	Medium (2)
	FS-CIPS-012.21		Download/Extract in a file outside Eudamed information details of submitted measures taken displayed in Eudamed	-	Nice to have	Low (3)
FS-CIPS-013 : Machine to machine (M2M) CI/PS information upload	FS-CIPS-013.01	Sponsor	Import using a M2M web service CI/PS sponsor own information from their database to Eudamed for application/notification/change/substantial modification submission	-	Nice to have	Low (3)
	FS-CIPS-013.02		Import using a M2M web service CI/PS sponsor own information from their database to Eudamed for adverse events submission	-	Nice to have	Medium (2)
	FS-CIPS-013.03		Import using a M2M web service CI/PS sponsor own information from their database to Eudamed for their CI/PS reports and summary submission	-	Nice to have	Low (3)
	FS-CIPS-013.04	Competent authority	Import using a M2M web service own measures taken (Revoke of authorisation, Suspension or termination, Required modifications) by that CA from their national MS database to Eudamed for providing and communicating their measures taken.	LR-CIPS-039 LR-NFS-002	Necessary	Medium (2)
	FS-CIPS-013.05		Import using a M2M web service Coordinating CA for a single CI/PS application own final assessment report from their national MS database to Eudamed for entering and transmitting their final assessment report and notification date.	LR-CIPS-048 LR-NFS-002	Necessary	Medium (2)

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	FS-CIPS-013.06		Import using a M2M web service own disagreement information by that CA for an authorisation by the CMS for a single CI/PS from their national MS database to Eudamed for entering and communicating their disagreement.	LR-CIPS-046 LR-NFS-002	Necessary	Medium (2)
	FS-CIPS-013.07		Import using a M2M web service CA own decision and related information and/or time limit setting regarding validation and authorisation of CI/PS from their national MS database to Eudamed for providing their decision and/or time limit for CI/PS.	LR-CIPS-026 LR-CIPS-029 LR-CIPS-027 LR-CIPS-028 LR-CIPS-025 LR-CIPS-030 LR-CIPS-032 LR-CIPS-031 LR-NFS-002	Nice to have	Medium (2)
	FS-CIPS-013.08	Eudamed	Import using a M2M web service information (on identification of related clinical trials and medicinal products) on clinical trial from the EU database for clinical trials on medicinal products for human use as concerns combined CI of devices under MDR with a clinical trial under that Regulation or PS of companion diagnostic under IVDR.	LR-CIPS-038	Required	Medium (2)
FS-CIPS-014 : Machine to machine (M2M) CI/PS information download	FS-CIPS-014.01	Sponsor	Export using a M2M web service own information submitted for a CI/PS by that sponsor in Eudamed to that sponsor database.	-	Nice to have	Low (3)
	FS-CIPS-014.02		Export using a M2M web service own information submitted for an adverse event by that sponsor in Eudamed to that sponsor database.	-	Nice to have	Low (3)
	FS-CIPS-014.03		Export using a M2M web service own information submitted for a CI/PS report and its summary by that sponsor in Eudamed to that sponsor database.	-	Nice to have	Low (3)
	FS-CIPS-014.04	Competent authority	Export using a M2M web service information submitted for a CI/PS by sponsor together with related decisions and time limit setting by other CA in Eudamed to the national MS database of that CA	LR-CIPS-035 LR-NFS-002	Required	Medium (2)

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	FS-CIPS-014.05		Export using a M2M web service information submitted for an adverse event by sponsor in Eudamed to the national MS database of that CA	LR-CIPS-035 LR-NFS-002	Required	Medium (2)
	FS-CIPS-014.06		Export using a M2M web service information submitted for a CI/PS report and its summary by sponsor in Eudamed to the national MS database of that CA	LR-CIPS-035 LR-NFS-002	Required	Medium (2)
	FS-CIPS-014.07		Export using a M2M web service information submitted for measures taken (Revoke of authorisation, Suspension or termination, Required modifications) by another CA in Eudamed to the national MS database of that CA	LR-CIPS-039 LR-CIPS-035 LR-NFS-002	Required	Medium (2)
	FS-CIPS-014.08		Export using a M2M web service information submitted for a single CI/PS application final assessment report by another Coordinating CA in Eudamed to the national MS database of that CA	LR-CIPS-048 LR-CIPS-035 LR-NFS-002	Required	Medium (2)
	FS-CIPS-014.09		Export using a M2M web service information submitted for disagreement of authorisation by another CA for a single CI/PS application in Eudamed to the national MS database of that CA	LR-CIPS-046 LR-CIPS-035 LR-NFS-002	Required	Medium (2)

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8.1.5. Vigilance - VGL

Functional Specifications	#	Actors	Eudamed functional specification details (Eudamed shall allow/enable/transmit/assign/assist …)	Related requirements	Legal Priority	Timing priority
FS-VGL-001 : Manage PSUR (submission and evaluation)	FS-VGL-001.01	EU MF, Non-EU MF	Enable to enter and to submit a PSUR for own [class III or implantable medical devices]/[class D in vitro diagnostic medical devices] to the NB involved in the conformity assessment of the concerned devices.	LR-VGL-001	Required	Medium (2)
	FS-VGL-001.02	NB	Enable the designated (in the PSUR) NB to add its evaluation attached to a PSUR with details of any action taken. Inform and make available the PSUR and its evaluation by the NB to the CAs and the MF.	LR-VGL-014	Required	Medium (2)
FS-VGL-002 : Manage Trend Reports (submission and assessment)	FS-VGL-002.01	EU MF, Non-EU MF (AR)	Enable the submission of an initial, follow-up and final (and possibly combined) Trend Report and if applicable. Make available the Trend report submitted by a MF/AR to the CA(s) concerned and to the NB(s) that issued the certificate(s) of the device(s) included in the Trend report and inform the CA(s) and NB(s) concerned.	LR-VGL-009 LR-VGL-010 LR-VGL-015	Required	Medium (2)
	FS-VGL-002.02	CA	Enable CA(s) to enter its own assessment on a Trend Report including measures to ensure public health and safety. Make accessible and inform the MF concerned and the other CAs of the CA assessment outcome.	LR-VGL-017 LR-VGL-018 LR-VGL-011	Necessary	Low (3)
FS-VGL-003 : Manage PSRs	FS-VGL-003.01	EU MF, Non-EU MF (AR)	Enable the MF/AR to enter, to submit and update PSR for serious incidents relating to its devices together with the conditions and agreement of the CA coordinating the PSR or the CA concerned if about only one MS concerned. Make available the PSR submitted by the MF/AR to the CAs participating in the PSR and to the NB(s) that issued the certificate(s) of the device(s) included in the PSR and inform the CA(s) and NB(s) concerned.	LR-VGL-007	Required	Medium (2)

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FS-VGL-004 : Manage serious incidents reports (submission and assessment).	FS-VGL-004.01	EU MF, Non-EU MF (AR)	Enable the MF/AR to enter and to submit an initial, follow up (updates), combined initial and final and/or a final serious incident report, final non-reportable for one of its devices (with check and warning for a possible duplicate of the incident report). Enable the MF/AR to provide to the CA final incident reports with its findings from the investigation setting out with conclusions. Make accessible and inform the CAs of any serious incident report submitted by a MF/AR, and the NB having issued a certificate for a device involved. The reported SI should be send to the CA of the MS where the incident occurred	LR-VGL-002 LR-VGL-004 LR-VGL-012 LR-VGL-015	Required	High (1)
	FS-VGL-004.02	CA	Enable CA to enter and to submit its assessment to a serious incident (with their own IMDRF nomenclatures codes) provided that the incident has occurred in the territory of its Member State. Make accessible and inform the MF, the AR and the other CAs of the CA assessment of a serious incident submitted by a MF/AR.	LR-VGL-019 LR-VGL-015	Required	High (1)
FS-VGL-005 : Manage FSCAs (submission and assessment)	FS-VGL-005.01	EU MF, Non-EU MF (AR)	Enable the MF/AR to enter and to submit an initial, follow up (updates) and/or a final FSCA report related to a FSCA undertaken in the Union market including one undertaken in a third country (with check and warning for a possible duplicate of the incident report). Enable the MF/AR to provide to the CA final FSCA reports with its findings from the investigation setting out with conclusions and corrective actions to be taken. Make accessible and inform all CAs of any FSCA report submitted by a MF/AR, and the NB having issued a certificate for a device involved.	LR-VGL-005 LR-VGL-028 LR-VGL-015	Required	High (1)

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	FS-VGL-005.02	CA	Enable CA to enter and to submit its assessment for an FSCA implemented in its Member State (and/or that the MF/AR is established in its country). Make accessible and inform the MF, the AR and the other CAs of the CA assessment of a FSCA submitted by a MF/AR.	LR-VGL-019 LR-VGL-015	Required	High (1)
FS-VGL-006 : Manage FSNs	FS-VGL-006.01	EU MF, Non-EU MF (AR)	Enable the MF/AR to enter and to submit a draft FSN subject to comments by the evaluating CA(s) (or if applicable the coordinating CA) relating to FSCA(s) he has already submitted. Make accessible and inform the CA(s) concerned of draft FSN submitted by a MF/AR, and the NB having issued a certificate for a device involved.	LR-VGL-013 LR-VGL-015	Necessary	High (1)
	FS-VGL-006.02		Enable the MF/AR to enter and to submit over a period of time a final FSN in all concerned languages that will be accessible to the public at submission relating to FSCA(s) he has already submitted. Make accessible and inform the CA(s) concerned of final FSN submitted by a MF/AR, and the NB having issued a certificate for a device involved.	LR-VGL-013 LR-VGL-015	Required	High (1)
	FS-VGL-006.03	CA	Enable the CA (evaluating or coordinating) to enter and to submit comments to a draft FSN within a standardized pre-set time period submitted by a MF/AR. Make accessible and inform the MF, the AR and the other CA(s) concerned of comments submitted by the CA to a draft FSN, and the NB having issued a certificate for a device involved.	LR-VGL-013 LR-VGL-015	Necessary	High (1)
FS-VGL-007 : Manage coordinated assessment procedure	FS-VGL-007.01	CA	Enable a CA to indicate it has assumed the role of the Coordinating CA (CCA) for serious incident reports and/or FSCA reports and to inform the MF, the AR, the other CAs and the Commission	LR-VGL-020	Required	Medium (2)

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FS-VGL-008 : Machine to Machine (M2M) vigilance and post-market surveillance information upload	FS-VGL-008.01	EU MF, Non-EU MF (AR)	Enable the MF to upload (M2M) a proposed PSUR for its validation by a NB.	LR-VGL-001	Nice to have	Medium (2)
	FS-VGL-008.02		Enable the MF/AR to upload (M2M) initial, follow-up and final (and possibly combined) trend report.	LR-VGL-009	Necessary	Medium (2)
	FS-VGL-008.03		Enable the MF/AR to upload (M2M) PSR.	LR-VGL-007	Necessary	Medium (2)
	FS-VGL-008.04		Enable the MF/AR to upload (M2M or with XML file) an initial, follow up (updates), combined initial and final and/or a final serious incident report	LR-VGL-002	Necessary	High (1)
	FS-VGL-008.05		Enable the MF/AR to upload (M2M or with XML file) an initial, follow up (updates) and/or a final FSCA report	LR-VGL-005	Necessary	High (1)
	FS-VGL-008.06		Enable the MF/AR to upload (M2M) proposed draft FSN for comments by CA or final FSN for public access.	LR-VGL-013	Necessary	High (1)
	FS-VGL-008.07	NB	Enable the NB to upload (M2M) its evaluation attached to a PSUR with details of any action taken	LR-VGL-014	Necessary	Medium (2)
	FS-VGL-008.08	CA	Enable the CA to upload (M2M) the outcome of its assessment for incidents and FSCAs including corrective action taken or envisaged by the manufacturer or required of it	LR-VGL-019 LR-NFS-002	Required	Medium (2)
	FS-VGL-008.09		Enable the CA to upload (M2M) comments to a draft FSN submitted by a MF/AR	LR-VGL-013 LR-NFS-002	Necessary	High (1)
FS-VGL-009 : Machine to Machine (M2M) vigilance and post-market surveillance information download	FS-VGL-009.01	NB	Enable downloading (M2M) of an initial, follow up (updates), combined initial and final and/or a final serious incident report submitted by a MF/AR, involving a device for which it has issued the certificate	LR-VGL-003 LR-VGL-015	Required	Medium (2)
	FS-VGL-009.02		Enable downloading (M2M) of an initial, follow up (updates), and/or a final FSCA report submitted by a MF/AR, for devices for which it has issued the certificate	LR-VGL-006 LR-VGL-015	Required	Medium (2)
	FS-VGL-009.03		Enable downloading (M2M) of a PSR submitted by a MF/AR involving a device for which it has issued the certificate	LR-VGL-008 LR-VGL-015	Required	Low (3)

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	FS-VGL-009.04		Enable downloading (M2M) of a initial, follow-up and final (and possibly combined) Trend report submitted by a MF/AR involving a device for which it has issued the certificate	LR-VGL-011 LR-VGL-015	Required	Low (3)
	FS-VGL-009.05		Enable downloading (M2M) of a PSUR submitted by a MF for evaluation by the NB	LR-VGL-014	Necessary	Medium (2)
	FS-VGL-009.06	CA	Enable downloading (M2M) of an initial, follow up (updates), combined initial and final and/or a final serious incident report submitted by a MF/AR that occurred in its Member State and/or for which the MF/AR is established in its country	LR-VGL-003 LR-NFS-002	Required	High (1)
	FS-VGL-009.07		Enable downloading (M2M) of an initial, follow up (updates), and/or a final FSCA report submitted by a MF/AR implemented/to be implemented in its Member State and/or for which the MF is established in its country.	LR-VGL-006 LR-NFS-002	Required	High (1)
	FS-VGL-009.08		Enable downloading (M2M) of a draft or final FSN submitted by a MF/AR together with existing comments coming from other CA(s)	LR-NFS-002	Required	High (1)
	FS-VGL-009.09		Enable downloading (M2M) of a PSR to the CA of the MS(s) in which the incidents occurred (when the incidents occurred only in one MS) or the CAs agreed in the PSR and the CA of the MS in which the MF/AR has its registered place of business	LR-VGL-008 LR-NFS-002	Required	Medium (2)
	FS-VGL-009.10		Enable downloading (M2M) of a Trend report submitted by a MF/AR to the CA of the MS in which the incident occurred.	LR-VGL-011 LR-NFS-002	Required	Medium (2)
	FS-VGL-009.11		Enable downloading (M2M) of a PSUR submitted by a MF together with the evaluation of the NB	LR-VGL-016 LR-NFS-002	Required	Medium (2)

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	FS-VGL-009.12		Enable downloading (M2M) the outcome of the assessment from other CA(s) for incidents and FSCAs including corrective action taken or envisaged by the manufacturer or required of it	LR-VGL-019 LR-NFS-002	Required	High (1)
	FS-VGL-009.13	EU MF, non-EU MF (AR)	Enable downloading (M2M) of an initial, follow up (updates), combined initial and final and/or a final serious incident report submitted by this MF/AR	-	Nice to have	Low (3)
	FS-VGL-009.14		Enable downloading (M2M) of an initial, follow up (updates), and/or a final FSCA report submitted by this MF/AR	-	Nice to have	Low (3)
	FS-VGL-009.15		Enable downloading (M2M) of a PSR submitted by this MF/AR	-	Nice to have	Low (3)
	FS-VGL-009.16		Enable downloading (M2M) of a Trend report submitted by this MF/AR	-	Nice to have	Low (3)
	FS-VGL-009.17		Enable downloading (M2M) of a PSUR submitted by this MF	-	Nice to have	Low (3)
FS-VGL-010 : Search and view post-market surveillance and vigilance information	FS-VGL-010.01	CA, EC	Enable to search among list of PSURs submitted by MFs (including the evaluation of the NB), PSRs	LR-VGL-016 LR-VGL-021 LR-VGL-023	Required	Medium (2)
	FS-VGL-010.02		Display information details of a PSUR submitted by the MF with the evaluation of the NB	LR-VGL-016 LR-VGL-021 LR-VGL-023	Required	Medium (2)
	FS-VGL-010.03		Enable to search among list of Serious incident reports submitted by MF/ARs (including CA evaluations)	LR-VGL-021 LR-VGL-023	Required	High (1)

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	FS-VGL-010.04		Display information details of a serious incident report submitted by a MF/AR with the evaluation(s) of the CA(s)	LR-VGL-021 LR-VGL-023	Required	High (1)
	FS-VGL-010.05		Enable to search among list of FSCA and FSN submitted by MF/ARs (including CA evaluations)	LR-VGL-021 LR-VGL-023	Required	High (1)
	FS-VGL-010.06		Display information details of a FSCA including the FSN submitted by a MF/AR with the evaluation(s)/comments of the CA(s)	LR-VGL-021 LR-VGL-023	Required	High (1)
	FS-VGL-010.07		Enable to search among list of Trend reports submitted by MF/ARs (including CA assessment outcome))	LR-VGL-021 LR-VGL-023	Required	Medium (2)
	FS-VGL-010.08		Display information details of a trend report submitted by a MF/AR with the assessment outcome(s) of the CA(s)	LR-VGL-021 LR-VGL-023	Required	Medium (2)
	FS-VGL-010.09		Enable to search among list of PSRs submitted by MF/ARs	LR-VGL-021 LR-VGL-023	Required	Medium (2)
	FS-VGL-010.10		Display information details of a PSR submitted by a MF/AR with the conditions and agreement(s) of CA(s)	LR-VGL-021 LR-VGL-023	Required	Medium (2)
	FS-VGL-010.11		Enable to search among list of outcomes of the assessment entered/submitted by the CA and submitted by other CA(s) for incidents and FSCAs including corrective action taken or envisaged by the manufacturer or required of it	LR-VGL-021 LR-VGL-023	Required	High (1)
	FS-VGL-010.12		Display information details of an outcome of the assessment submitted by the CA and other CA(s) for a given serious incident or FSCAs including corrective action taken or envisaged by the manufacturer or required of it	LR-VGL-021 LR-VGL-023	Required	High (1)

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	FS-VGL-010.13	NB	Enable to search among list of PSURs submitted by MFs to be reviewed or being reviewed by the NB.	LR-VGL-014 LR-VGL-015	Required	Medium (2)
	FS-VGL-010.14		Display information details of a PSUR submitted by the MF to be reviewed or being reviewed by the NB with the evaluation of the NB	LR-VGL-014 LR-VGL-015	Required	Medium (2)
	FS-VGL-010.15		Enable to search among list of Serious incident reports submitted by MFs/ARs involving a device for which the NB has issued the certificate	LR-VGL-015	Required	High (1)
	FS-VGL-010.16		Display information details of a serious incident report submitted by a MF/AR involving a device for which the NB has issued the certificate	LR-VGL-015	Required	High (1)
	FS-VGL-010.17		Enable to search among list of FSCA and FSN submitted by MFs/ARs involving a device for which the NB has issued the certificate	LR-VGL-015	Required	High (1)
	FS-VGL-010.18		Display information details of a FSCA including the FSN submitted by a MF/AR involving a device for which the NB has issued the certificate	LR-VGL-015	Required	High (1)
	FS-VGL-010.19		Enable to search among list of Trend reports submitted by MFs/ARs involving a device for which the NB has issued the certificate	LR-VGL-015	Required	Medium (2)
	FS-VGL-010.20		Display information details of a trend report submitted by a MF/AR involving a device for which the NB has issued the certificate	LR-VGL-015	Required	Medium (2)
	FS-VGL-010.21		Enable to search among list of PSRs submitted by MFs/ARs involving a device for which the NB has issued the certificate	LR-VGL-015	Required	Medium (2)

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	FS-VGL-010.22		Display information details of a PSR submitted by a MF/AR with the conditions and agreement(s) of CA(s) involving a device for which the NB has issued the certificate	LR-VGL-015	Required	Medium (2)
	FS-VGL-010.23	EU, non EU MF, AR	Enable to search among list of PSURs entered/submitted by the MF (including the evaluation of the NB).	LR-VGL-001	Necessary	Medium (2)
	FS-VGL-010.24		Display information details of a PSUR entered/submitted by the MF with the evaluation of the NB if available	LR-VGL-001	Necessary	Medium (2)
	FS-VGL-010.25		Enable to search among list of Serious incident reports referencing the MF/AR	LR-VGL-002	Necessary	High (1)
	FS-VGL-010.26		Display information details of a serious incident report referencing the MF/AR	LR-VGL-002	Necessary	High (1)
	FS-VGL-010.27		Enable to search among list of FSCA and FSN referencing the MF/AR	LR-VGL-005 LR-VGL-013	Necessary	High (1)
	FS-VGL-010.28		Display information details of a FSCA including the FSN referencing the MF/AR	LR-VGL-005 LR-VGL-013	Necessary	High (1)
	FS-VGL-010.29		Enable to search among list of Trend reports referencing the MFs/ARs	LR-VGL-009	Necessary	Medium (2)
	FS-VGL-010.30		Display information details of a Trend report referencing the MF/AR	LR-VGL-009	Necessary	Medium (2)

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	FS-VGL-010.31		Enable to search among list of PSRs referencing the MF/AR	LR-VGL-007	Necessary	Medium (2)
	FS-VGL-010.32		Display information details of a PSR referencing the MF with the conditions and agreement(s) of CA(s)	LR-VGL-007	Necessary	Medium (2)
FS-VGL-011 : Grant CAs of third countries or International organisations, appropriate access level to Eudamed	FS-VGL-011.01	EC	Enable the Commission to grant specific access levels to third country CA or international organisation to access specific post-market surveillance and vigilance information available in Eudamed.	LR-VGL-024	Required	Low(3)
FS-VGL-012 : Analysis of vigilance data	FS-VGL-012.01	Commission	Monitor data	LR-VGL-022	Necessary	Medium (2)
	FS-VGL-012.02	CA	Obtain monitored data in order to identify trends, patterns or signals	LR-VGL-022	Necessary	Medium (2)

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8.1.6. Market Surveillance – MSU

Functional Specifications	#	Actors	Eudamed functional specification details (Eudamed shall allow/enable/transmit/assign/assist …)	Related requirements	Legal Priority	Timing priority
FS-MSU-001 : Manage the annual summaries of the results of the surveillance activities of the MS	FS-MSU-001.01	CA	Enable to enter/upload a document consisting in an annual summary of the results of their surveillance activities with its attributes (meta-data)	LR-MSU-001	Required	Medium (2)
	FS-MSU-001.02		Allow through submission to make accessible, notify and transmit an annual summary of the results of their surveillance activities to all other concerned CAs	LR-MSU-002 LR-MSU-014	Required	Medium (2)
FS-MSU-002 : Manage the final inspection reports of the MS	FS-MSU-002.01	CA	Enable to enter/upload a document consisting in a final inspection report with its attributes (meta-data)	LR-MSU-003	Required	Medium (2)
	FS-MSU-002.02		Allow through submission to make accessible, notify and transmit a final inspection report to all other concerned CAs	LR-MSU-015	Required	Medium (2)
FS-MSU-003 : Manage the summaries of the results of the reviews and assessment of the market surveillance activities of the MS	FS-MSU-003.01	CA	Enable to enter/upload a document consisting in a summary of the results of the reviews and assessment of the market surveillance activities of the MS with its attributes (meta-data)	LR-MSU-004	Required	Medium (2)
	FS-MSU-003.02		Allow through submission to make accessible to all including the public and notify and transmit a summary of the results of the reviews and assessment of the market surveillance activities of the MS to all other concerned CAs	LR-MSU-016 LR-MSU-005	Required	Medium (2)
FS-MSU-004 : Communicate results of the review and assessment by the MS of the functioning of its market	FS-MSU-004.01	CA	Enable to enter/upload a document consisting in the results of the reviews and assessment of the market surveillance activities of the MS with its attributes (meta-data)	LR-MSU-006	Necessary	Medium (2)

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surveillance activities	FS-MSU-004.02		Allow through submission to make accessible and communicate results of the reviews and assessment of the market surveillance activities of the MS to all other CAs and the Commission	LR-MSU-006	Necessary	Medium (2)
FS-MSU-005 : Manage notification and exchange information on devices presenting an unacceptable risk to health and safety	FS-MSU-005.01	CA	Enable to enter information of the results of the evaluation and of the actions required from the economic operator for devices identified by the CA as presenting an unacceptable risk to health and safety	LR-MSU-007 LR-MSU-009	Required	Medium (2)
	FS-MSU-005.02		Enable to enter information of the measure taken by the CA for device presenting an unacceptable risk to health and safety where the economic operator does not take adequate corrective action within the allowed period	LR-MSU-008 LR-MSU-009	Required	Medium (2)
	FS-MSU-005.03		Enable to enter additional relevant information at their disposal relating to the non-compliance and of any measures adopted by them in relation to the device concerned when the CA is not the one initiating the procedure for a device presenting an unacceptable risk to health and safety	LR-MSU-010	Required	Medium (2)
	FS-MSU-005.04		Enable to enter their objections to notified national measures for a device identified by another CA as presenting an unacceptable risk to health and safety	LR-MSU-011	Required	Medium (2)
	FS-MSU-005.05		Allow through submission to make accessible, notify and transmit a notification or measures or objections on devices presenting an unacceptable risk to health and safety to all other concerned CAs and to the NB that issued a certificate for the concerned device and its designating authority	LR-MSU-017 LR-MSU-018 LR-MSU-019 LR-MSU-020 LR-MSU-025	Required	Medium (2)
FS-MSU-006 : Manage information on measures taken for a non-compliant device not presenting an unacceptable risk to health or safety or other aspects of	FS-MSU-006.01	CA	Enable to enter information on measures taken for a non-compliant device not presenting an unacceptable risk to health or safety or other aspects of the protection of public health (other non-compliance) where the economic operator does not bring the non-compliance to an end within the allowed period	LR-MSU-012	Required	Medium (2)

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the protection of public health (other non-compliance)	FS-MSU-006.02		Allow through submission to make accessible, inform and transmit information on measures taken for a non-compliant device not presenting an unacceptable risk to health or safety or other aspects of the protection of public health (other non-compliance) and to the NB that issued a certificate for the concerned device and its designating authority	LR-MSU-021	Required	Medium (2)
FS-MSU-007 : Manage notification on preventive health protection measures	FS-MSU-007.01	CA	Enable to enter information on preventive health protection measures the MS has taken related to a device or a specific category or group of devices giving the reasons for its decision	LR-MSU-013	Required	Medium (2)
	FS-MSU-007.02		Allow through submission to make accessible, notify and transmit information on preventive health protection measures the MS has taken related to a device or a specific category or group of devices giving the reasons for its decision	LR-MSU-022	Required	Medium (2)
FS-MSU-008 : Search and view information on market surveillance	FS-MSU-008.01	NB, DA of the NB	Search among lists of devices identified by a CA as presenting an unacceptable risk to health and safety, or with preventive health protection measures or other non-compliance for which the NB has issued a certificate	LR-MSU-007 LR-MSU-008 LR-MSU-012 LR-MSU-013 LR-MSU-025 LR-MSU-026	Required	Medium (2)
	FS-MSU-008.02		Display information details on a notification for a device, for which the NB has issued a certificate, presenting an unacceptable risk to health and safety or with preventive health protection measures or other non-compliance and possible measures taken by the CA concerned	LR-MSU-007 LR-MSU-008 LR-MSU-012 LR-MSU-013 LR-MSU-025 LR-MSU-026	Required	Medium (2)
	FS-MSU-008.03		Search and view a document consisting in a summary of the results of the reviews and assessment of the market surveillance activities of a MS with its attributes	LR-MSU-005	Necessary	Medium (2)
	FS-MSU-008.04	CA, EC	Search among lists of devices and a list of manufacturers with devices identified by a CA as presenting an unacceptable risk to health and safety	LR-MSU-007 LR-MSU-008 LR-MSU-024	Required	Medium (2)
	FS-MSU-008.05		Display information details on a notification for a device presenting an unacceptable risk to health and safety and	LR-MSU-007 LR-MSU-008	Required	Medium (2)

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			possible measures taken by the CA concerned, additional information provided by other CAs and objections on national measures	LR-MSU-010 LR-MSU-011 LR-MSU-024		
	FS-MSU-008.06		Search among lists of devices identified by a CA as with other non-compliance than presenting an unacceptable risk to health and safety and not preventing health protection	LR-MSU-012 LR-MSU-024	Required	Medium (2)
	FS-MSU-008.07		Display information details on measures taken by a CA for a device with other non-compliance than presenting an unacceptable risk to health and safety and not preventing health protection	LR-MSU-012 LR-MSU-024	Required	Medium (2)
	FS-MSU-008.08		Search among lists of devices, category or group of devices identified by a CA as attached to preventive health protection measures the MS has taken	LR-MSU-013 LR-MSU-024	Required	Medium (2)
	FS-MSU-008.09		Display information details on preventive health protection measures taken by a CA for a device, category or group of devices	LR-MSU-013 LR-MSU-024	Required	Medium (2)
	FS-MSU-008.10		Search and view a document consisting in a summary of the results of the reviews and assessment of the market surveillance activities of a MS with its attributes	LR-MSU-005 LR-MSU-016 LR-MSU-024	Required	Medium (2)
	FS-MSU-008.11		Search and view a document consisting in the results of the reviews and assessment of the market surveillance activities of the MS with its attributes	LR-MSU-006 LR-MSU-024	Necessary	Medium (2)
	FS-MSU-008.12		Search and view a document consisting in an annual summary of the results of the surveillance activities of a MS with its attributes	LR-MSU-002 LR-MSU-014 LR-MSU-024	Required	Medium (2)
	FS-MSU-008.13		Search and view a document consisting in a final inspection report of a MS with its attributes	LR-MSU-003 LR-MSU-015 LR-MSU-024	Required	Medium (2)
FS-MSU-009 : Machine to machine (M2M) market surveillance data Download	FS-MSU-009.01	CA, NB	Export registered market surveillance data of CA in Eudamed to MS national database (and NBs if applicable)	LR-MSU-013 LR-MSU-014 LR-MSU-015 LR-MSU-016 LR-MSU-017 LR-MSU-018 LR-MSU-019	Required	Medium (2)

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				LR-MSU-020 LR-MSU-021 LR-MSU-022 LR-MSU-027		
FS-MSU-010 : Machine to machine (M2M) market surveillance data Upload	FS-MSU-010.01	CA	Import market surveillance own data from their MS national database to Eudamed	LR-NFS-002	Necessary	Medium (2)
FS-MSU-011 : Platform for cooperation and collaboration between MS and between MS and the Commission	FS-MSU-011.01	CA, EC	Enable to exchange any information between CAs and between the Commission and CAs in the field of market surveillance to enhance cooperation and collaboration	LR-NFS-002	Necessary	Low (3)

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8.1.7. Horizontal Features

Functional Specifications	#	Eudamed functional specification details (Eudamed shall allow/enable/transmit/assign/assist …)	Related requirements	Legal Priority	Timing Priority
FS-EUD-001 : User Interface	FS-EUD-001.01	Enable all users to select their preferred language for the user interface among the official languages of the Union	LR-EUD-003 LR-UDID-009 LR-CIPS-011	Required	High (1)
	FS-EUD-001.02	Eudamed set by default its User Interface to the preferred language of the user defined in its account details	LR-EUD-003 LR-UDID-009 LR-CIPS-011	Nice to have	High (1)
	FS-EUD-001.03	Assist users by displaying help and tooltips specific to every screen	LR-UDID-001 LR-UDID-003 LR-UDID-007 LR-UDID-004 LR-ACT-001 LR-ACT-002 LR-ACT-003 LR-ACT-006 LR-ACT-007 LR-ACT-008 LR-EUD-001	Necessary	High (1)
	FS-EUD-001.04	Assist users in entering data which comply with the constraints specific to each data field	LR-UDID-001 LR-UDID-003 LR-UDID-007 LR-UDID-004 LR-ACT-001 LR-ACT-002 LR-ACT-003 LR-ACT-006 LR-ACT-007 LR-ACT-008 LR-EUD-001	Necessary	High (1)
	FS-EUD-001.05	Display all information in Web pages, following standard and up-to-date User Interface practices	LR-EUD-001	Necessary	High (1)
FS-EUD-002 : Data validation	FS-EUD-002.01	Enable users to apply the necessary corrections if the draft data entered when rejected due to errors, by providing detailed descriptions of the latter	LR-EUD-001	Necessary	High (1)

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FS-EUD-003 : Data versioning/Tracking system	FS-EUD-003.01	Enable versioning of data and associated documents to keep the history of registered data, their updates and keep track on actions perform by the users (who/when for what)	LR-NFS-002 LR-NFS-003	Necessary	High (1)
FS-EUD-004 : Notification/Information email system	FS-EUD-004.01	Notify/Inform through email message to inform actors/users on actions that took place in Eudamed and/or that would require the action of a user/actor	LR-NFS-002 LR-NFS-003 LR-MSU-007 LR-MSU-008 LR-MSU-013	Required	High (1)
	FS-EUD-004.02	Notifications sent through email to actors / users on actions needed to be performed will contain a link to the item/ section from the EUDAMED site where the user will be able to obtain more information or where he will be able to complete the action requested	LR-NFS-002 LR-NFS-003 LR-MSU-007 LR-MSU-008 LR-MSU-013	Required	High(1)
FS-EUD-005 : Warning email system on time limits for actions	FS-EUD-005.01	Inform/Warn through email message actors/users on close time limit on the possibility or need for doing action in Eudamed	LR-NFS-002	Nice to have (inform for possibility) Necessary (warning need)	Medium (2) High(1)
FS-EUD-006 : User access management and User management	FS-EUD-006.01	Enable a user with a EU Login account to request access to Eudamed restricted as acting on behalf of a specific actor. Enable authentication by EU login of any user who wants to access Eudamed restricted Enable users to log on to access to Eudamed restricted (authorisation system) and to provide/update their own data. Eudamed restricted shall limit access and rights to authorised users only, according to their profile(s), the actor(s) to which they are associated and to possible more granular restrictions.	LR-NFS-002 LR-NFS-003	Necessary	High (1)
	FS-EUD-006.02	Enable delegation to a Local actor or user administrator (LAA/LUA) of an actor to grant/manage/remove access to Eudamed restricted to users acting on behalf of this actor.	LR-NFS-002 LR-NFS-003	Necessary	High (1)

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	FS-EUD-006.03	Enable identification of a user as a sub-contractor acting on behalf of an actor for data management in Eudamed restricted and not being an employee (or not working directly for) of this actor.	LR-NFS-002 LR-NFS-003	Necessary	High (1)
	FS-EUD-006.04	Enable a LAA/LUA of a sponsor to grant/remove access to users for a specific CI/PS of this sponsor. Enable a LAA/LUA of a CA to grant/remove access to users for a specific CI/PS associated to this CA	LR-NFS-002 LR-NFS-003	Necessary	High (1)
FS-EUD-007 : Data retention	FS-EUD-007.01	Manage data retention periods based on data classification levels	LR-IAM-002	Necessary	High (1)
FS-EUD-008 : Data protection	FS-EUD-008.01	Acknowledgement method to inform systems users about the personal data policies	LR-IAM-003 LR-IAM-010	Necessary	High (1)
	FS-EUD-008.02	Display data considering ownership, confidentiality and personal data protection	LR-IAM-004 LR-IAM-010 LR-VGL-025	Necessary	High (1)
	FS-EUD-008.03	Manage data considering ownership of data	LR-IAM-008 LR-IAM-010	Necessary	High (1)
	FS-EUD-008.04	Store data in a secure manner	LR-IAM-009 LR-IAM-010	Necessary	High (1)
	FS-EUD-008.05	Only request personal data required for the functioning of the system	LR-IAM-011	Necessary	High (1)
FS-EUD-009 : Data Access	FS-EUD-009.01	Access available to all data for Member states	LR-EUD-002	Necessary	High (1)
	FS-EUD-009.02	Access available to all data for the commission	LR-EUD-002	Necessary	High (1)

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8.2. Public site – PUB

8.2.1. Actor - ACT

Functional Specifications	#	Eudamed functional specification details (Eudamed shall list/display)	Related requirements	Legal Priority	Timing Priority
FS-PUB-ACT-001 : Search and view actor details	FS-PUB-ACT-001.01	List all Economic Operators and Sponsors (only those with authorised application for CI/PS) whose registered actor details match a set of search criteria provided by the user	LR-ACT-009 LR-ACT-015	Necessary	High (1)
	FS-PUB-ACT-001.02	Display registered actor details (excluding the confidential information) of an Economic Operator or Sponsor (only those with an authorised application for CI/PS) designated by his/her Single Registration Number/Actor ID or by some other combination of criteria allowing his/her unique identification	LR-ACT-009 LR-ACT-015	Required	High (1)

8.2.2. UDI/Device – UDID

Functional Specifications	#	Eudamed functional specification details (Eudamed shall allow/enable/list/display)	Related requirements	Legal Priority	Timing Priority
FS-PUB-UDID-001 : Search and view UDI-DI and Device data (including SS(C)P)	FS-PUB-UDID-001.01	List all (Basic) UDI-DIs and devices whose UDI-DI and Device data match a set of search criteria provided by the user	LR-UDID-009 LR-UDID-015	Necessary	High (1)
	FS-PUB-UDID-001.02	Display registered (Basic) UDI-DI data and Device data of a Device associated to a Basic UDI-DI (including SS(C)P) or uniquely identified by a combination of other criteria	LR-UDID-009	Required	High (1)
	FS-PUB-UDID-001.03	Allow to search and view medical devices nomenclature codes and their related information (name, description …)	LR-UDID-002	Necessary	High (1)
FS-PUB-UDID-002 : Download UDI-DI and Device data (including SS(C)P)	FS-PUB-UDID-002.01	Enable downloading in a file the registered (Basic) UDI-DI data and Device data of Devices associated to a search result (limited in size content)	LR-DTX-008	Required	High (1)

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8.2.3. Certificate & Notified Body – CRF

Functional Specifications	#	Eudamed functional specification details (Eudamed shall allow/enable)	Related requirements	Legal Priority	Timing Priority
FS-PUB-CRF-001 : View information about NBs	FS-PUB-CRF-001.01	Enable to view the list of NBs notified under MDR/IVDR and their subsidiaries. Provide a link to Nando for details on designation/notification, scope of designation (conformity assessment activities, types of devices).	LR-CRF-001 LR-CRF-018	Required	High (1)
FS-PUB-CRF-003 : Search and view certificates	FS-PUB-CRF-003.01	Enable the public to search and view information about certificates and refused certificates	LR-CRF-018	Required	High (1)
FS-PUB-CRF-004 : View MS's Summary Reports on NBs	FS-PUB-CRF-004.01	Allow to select and view for a specific MS, one of its Summary Reports on monitoring and on-site assessment activities regarding NBs and their subsidiaries.	LR-CRF-018	Required	High (1) Medium (2)
FS-PUB-CRF-005 : View both the expert panel opinion and the justification of the NB	FS-PUB-CRF-005.01	Enable the public to view the expert panel opinion and the written justification provided by the NB in case the NB did not follow the advice of the expert panel for a CECP in its conformity assessment report	LR-CRF-028 LR-CRF-029	Required	High (1)

8.2.4. Clinical Investigation – CIPS

Functional Specifications	#	Eudamed functional specification details (Eudamed shall enable/display/hide …)	Related requirements	Legal Priority	Timing Priority
FS-PUB-CIPS-001 : Search and view CI/PS (application/notification) information and related updates for related information made publicly available	FS-PUB-CIPS-001.01	Display list of applications/notifications for CI/PS that are made publicly available whatever is the outcome, except the withdrawn. Enable to filter among the list of applications/notifications for CI/PS from a set of search criteria defined by the user on proposed relevant and related meta-data available in Eudamed. Display the information details of a CI/PS report and its summary made publicly available. Provide links to related available information like adverse events and device deficiencies, CI/PS report and summary, and UDI/devices. All information about CI/PS applications/notifications and related updates shall be	LR-CIPS-057 LR-CIPS-058	Required	Medium (2)

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		accessible to all unless for all or parts confidentiality of the information is justified (personal data protection, commercially confidential information, effective supervision by MS). Exchange of information about CI/PS between the MS and between them and the Commission shall not be accessible to the public.			
FS-PUB-CIPS-002 : Search and view CI/PS reports and summaries made publicly available	FS-PUB-CIPS-002.01	Display list of CI/PS reports and their summaries that are made publicly available. Enable to filter among the list of CI/PS reports from a set of search criteria defined by the user on proposed relevant and related meta-data available in Eudamed. Display the information details of a CI/PS report and its summary made publicly available. The summary and the CI/PS report shall become publicly accessible through Eudamed at the latest when the device is registered in Eudamed and before it is placed on the market. In case of early termination or temporary halt, the summary and the report shall become publicly accessible immediately after submission. If the device is not registered in Eudamed within one year of the summary and the report having been entered in Eudamed, they shall become publicly accessible at that point in time.	LR-CIPS-058	Required	Medium (2)
FS-PUB-CIPS-003 : Search and view reported adverse events and device deficiencies and related updates for related information available for the public	FS-PUB-CIPS-003.01	Display list of reported adverse events and device deficiencies that are made publicly available. Enable to filter among the list of reported adverse events and device deficiencies from a set of search criteria defined by the user on proposed relevant and related data available in Eudamed. Display the information details of an adverse event or device deficiency made publicly available. All information about adverse events, device deficiencies and related updates shall be accessible to all unless for all or parts confidentiality of the information is justified (personal data protection, commercially confidential information, effective supervision by MS). Exchange of information about CI/PS and related information between the MS and between them and the Commission shall not be accessible to the public.	LR-CIPS-057	Required	Medium (2)

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FS-PUB-CIPS-004 : Protect subjects data	FS-PUB-CIPS-004.01	Hide confidential/personal information from the public about subjects	LR-CIPS-059	Required	High (1)

8.2.5. Vigilance – VGL

Functional Specifications	#	Eudamed functional specification details (Eudamed shall enable/display)	Related requirements	Legal Priority	Timing Priority
FS-PUB-VGL-001 : Search and view vigilance and post-market surveillance information	FS-PUB-VGL-001.01	Enable the public (including healthcare professionals) to search and view with the appropriate level of access (*) the vigilance and post-market surveillance information. *To determine, it is to be defined what vigilance and post-market surveillance information could be available to the public. As long as there is no agreement among MS and with the Commission, these data will not be publically available.	LR-VGL-027	Required	Medium (2)
FS-PUB-VGL-002 : Search and view FSNs	FS-PUB-VGL-002.01	Enable the public to search for final FSNs from a set of search criteria defined by the user on proposed relevant and related meta-data available in Eudamed for final FSNs. Display the information details of a final FSN made publicly available Display list of final FSNs associated to a device	LR-VGL-026	Required	High (1)

8.2.6. Market Surveillance – MSU

Functional Specifications	#	Eudamed functional specification details (Eudamed shall enable/list/hide …)	Related requirements	Legal Priority	Timing Priority
FS-PUB-MSU-001 : Search and view a summary of the results of the reviews and assessments of the market surveillance activities of a MS	FS-PUB-MSU-001.01	List all summaries of the results of the reviews and assessments of the market surveillance activities of a MS	LR-MSU-005	Necessary	Medium (2)
	FS-PUB-MSU-001.02	Enable to open/download a document representing a summary of the results of the reviews and assessments of the market surveillance activities of a MS	LR-MSU-005	Required	Medium (2)
	FS-PUB-MSU-001.03	Hide confidential information from the public site related to Member state market surveillance data	LR-MSU-023	Required	High (1)

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8.2.7. Horizontal Features

Functional Specifications	#	Eudamed functional specification details (Eudamed shall enable/display)	Related requirements	Legal Priority	Timing Priority
FS-PUB-EUD-001 : User interface	FS-PUB-EUD-001.01	Enable all users to select their preferred language for the user interface among the official languages of the Union	LR-EUD-003 LR-UDID-009 LR-CIPS-011	Required	High (1)
	FS-PUB-EUD-001.02	Display all information in Web pages, following standard and up-to-date User Interface practices	LR-EUD-001	Necessary	High (1)

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9. Non-Functional Specifications - NFS

#	Specifications	Eudamed non-functional specification details	Related requirements	Legal Priority	Timing Priority
NFS-EUD-001.01	System performance and scalability	Performance and scalability shall be defined during the preparation of the detailed requirements	LR-NFS-001	Necessary	High (1)
NFS-EUD-002.01	Module integration	Eudamed, as a unified electronic system, shall enable sharing and associating data among all its functional modules	LR-NFS-002	Required	High (1)
NFS-EUD-003.01	System maintenance	Enable the Commission to ensure the maintenance of Eudamed	LR-NFS-003	Required	High (1)

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