MDCG 2022-12

Guidance on harmonised administrative practices and alternative technical solutions until Eudamed is fully functional (for Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices)

July 2022

INTRODUCTION

Article 33 of Regulation (EU) 2017/745 on medical devices[1] (MDR) and Article 30 of Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR)[2] requires the Commission to set up a European database on medical devices ('Eudamed'). According to paragraph 2 of those Articles, Eudamed will be composed of six different electronic systems (so called 'modules'), which facilitate the collation and processing of information under the MDR and IVDR regarding the registration of relevant economic operators (actor registration), devices and systems and procedure packs (UDI), notified bodies & certificates, certain aspects of conformity assessment, clinical investigations, performance studies, vigilance and market surveillance as well as post-market surveillance.

On 30 October 2019, the Commission published a notice[3] by which it concluded that the full functionality of Eudamed requires the availability and full operation of all six modules, both individually and jointly.

Article 113(3)(f) of Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR) addresses the possibility that Eudamed is not fully functional on the date of application of the IVDR (26 May 2022). Accordingly, the obligations and requirements in the IVDR that relate to Eudamed shall apply from the date corresponding to six months after the date of publication of the notice referred to in Article 34(3) MDR – notice of full functionality of Eudamed. Until Eudamed is fully functional, the IVDR stipulates that the corresponding provisions of Directive 98/79/EC[4] shall continue to apply for the purpose of meeting the obligations laid down in the provisions of Article 113(3)(f) IVDR regarding the exchange of information.

In addition, Article 113(3)(a) IVDR clarifies that Article 26(3) IVDR on the registration of devices, and Article 51(5) IVDR on the registration of certificates, start to apply 24 months after the date of publication of the notice referred to in Article 34(3) MDR.

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117, 5.5.2017, p. 1–175.

[2] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

[3] Available at: https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/eudamed_en.

[4] Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, OJ L 331, 7.12.1998, p. 1–37

SCOPE

This document provides guidance to Member States and other relevant parties on the application of certain IVDR provisions during the absence of Eudamed. To that end, this guidance intends to describe harmonised administrative practices and alternative technical solutions for the exchange of information until Eudamed becomes fully functional.

The proposed practices and solutions aim to enable Member States and other relevant parties to meet their obligations under the IVDR effectively while minimising any potential additional burden on the parties concerned. This guidance addresses in particular cases where the exchange of information would be difficult, or even not possible, to achieve based on the corresponding provisions of Directive 98/79/EC. The proposed practices and solutions set out in this document do not affect the general obligations of the parties to comply with the applicable requirements under the IVDR.

Whenever this guidance makes reference to CircaBC[5] as alternative solution, the Commission and other relevant parties should endeavour to make use of already existing CircaBC directories to the extent that this is possible and appropriate.

Parties should also take note of the MDCG Position Paper on the use of the Eudamed actor registration module and of the Single Registration Number (SRN) in the Member States.[6]

[5] CircaBC is available following this link.
[6] MDCG Position Paper available following this link: MDCG 2020-15

Article	Provisions related to the use of Eudamed (as referred to in Art. 113 (3) (f) IVDR)	Alternative solutions to submit and/or exchange information (as required under the IVDR)	Responsible actor(s)
Article 26: *Registration of devices*	1. Before placing a device, on the market, the manufacturer shall, in accordance with the rules of the issuing entity referred to in Article 24(2), assign a Basic UDI-DI as defined in Part C of Annex VI to the device and shall provide it to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that device. 2. For devices that are the subject of a conformity assessment as referred to in Article 48(3) and (4), in the second subparagraph of Article 48(7), Article 48(8) and the second subparagraph of Article 48(9), the assignment of a Basic UDI-DI referred to in paragraph 1 of this Article shall be done before the manufacturer applies to a notified body for that assessment. For the devices referred to in the first subparagraph, the notified body shall include a reference to the Basic UDI-DI on the certificate issued in accordance with point (a) of Section 4 of Annex XII and confirm in Eudamed that the information referred to in Section 2.2 of Part A of Annex VI is correct. After the issuing of the relevant certificate and before placing the device on the market, the	**Paragraphs 1-3:** **Note:** The functionality is available in Eudamed. The system may be used (on voluntary basis) for registration of devices even before the notice of full functionality of Eudamed has been published. Nevertheless, manufacturers should refer to the national provisions in Member States establishing product registration schemes. Manufacturers should note that the obligation of UDI assignment (Basic UDI and UDI-DI) to a device applies from 26 May 2022 (Art. 24(3) IVDR). Labelling requirements apply gradually, starting from 26 May 2023, according to the timelines set out in Art. 113(3)(e) IVDR.	**Manufacturers** (device registration, assignment and labelling)

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	manufacturer shall provide the Basic UDI-DI to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that device. 3. Before placing a device on the market, the manufacturer shall enter or, if already provided, verify in Eudamed the information referred to in Section 2 of Part A of Annex VI, with the exception of Section 2.2 thereof, and thereafter shall keep the information updated.		
Article 28: *Registration of manufacturers, authorised representatives and importers*	1. Before placing a device, on the market, manufacturers, authorised representatives and importers shall, in order to register, submit to the electronic system referred to in Article 30 the information referred to in Section 1 of Part A of Annex VI […]In cases where the conformity assessment procedure requires the involvement of a notified body pursuant to Article 48, the information referred to in Section 1 of Part A of Annex VI shall be provided to that electronic system before applying to the notified body. 2. […] the competent authority shall obtain a single	**Paragraphs 1-3:** **Note:** The functionality is available in Eudamed. The system may be used (on voluntary basis) for the registration of manufacturers, authorised representatives and importers even before the notice of full functionality of Eudamed has been published. Nevertheless, manufacturers, authorised representatives and importers should refer to the national provisions in Member States. Please refer to *MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States.*	**Economic operators** (registration) **Member States** (issuing)

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	registration number ('SRN') from the electronic system referred to in Article 27 and issue it to the manufacturer, the authorised representative or the importer. 3. The manufacturer shall use the SRN when applying to a notified body for conformity assessment and for accessing Eudamed in order to fulfil its obligations under Article 26. […]		
Article 29: *Summary of safety and performance*	1. For class C and D devices, other than devices for performance studies, the manufacturer shall draw up a summary of safety and performance. The summary of safety and performance shall be written in a way that is clear to the intended user and, if relevant, to the patient and shall be made available to the public via Eudamed. The draft of the summary of safety and performance shall be part of the documentation to be submitted to the notified body involved in the conformity assessment pursuant to Article 48 and shall be validated by that body. After its validation, the notified body shall upload the summary to Eudamed. The manufacturer shall mention on the	**Paragraph 1:** The SSP shall be made available to the public upon request without undue delay, or the manufacturer shall specify where it is made available to the public. **Note:** The functionality is available in Eudamed. The system may be used (on voluntary basis) for the upload of the SSP even before the notice of full functionality of Eudamed has been published.	**Manufacturers** **Notified Bodies**

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	label or instructions for use where the summary is available. 2. The summary of safety and performance shall include at least the following aspects: (a) the identification of the device and the manufacturer, including the Basic UDI-DI and, if already issued, the SRN; […]	**Paragraph 2:** Please refer to alternative solution for Art. 28.	
Article 30: *European database on medical devices*	[…] 2. Eudamed shall include the following electronic systems: (a) the electronic system for registration of devices referred to in Article 26; (b) the UDI-database referred to in Article 25; (c) the electronic system on registration of economic operators referred to in Article 27; (d) the electronic system on notified bodies and on certificates referred to in Article 52; (e) the electronic system on performance studies referred to in Article 69; (f) the electronic system on vigilance and post-market surveillance referred to in Article 87; (g) the electronic system on market surveillance	**Paragraph 2:** The submission in Eudamed of the different sets of required information is possible (on a voluntary basis) for the features made available by the Commission before the notice referred to in Article 34(3) MDR. (see introductory text).	-

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	referred to in Article 95.		
Article 36: *Nomination of experts for joint assessment of applications for notification*	[…] 2. The Commission shall maintain a list of the experts nominated pursuant to paragraph 1 of this Article, together with information on their specific field of competence and expertise. That list shall be made available to Member States competent authorities through the electronic system referred to in Article 52.	**Paragraph 2:** The Commission has made available the list to Member States by means of a dedicated secure directory in the Communication and Information Resources Centre for Administrations, Businesses and Citizens (CircaBC).	**Commission** (CircaBC)
Article 38: *Designation and notification procedure*	[…] 10. When publishing the notification in NANDO, the Commission shall also add to the electronic system referred to in Article 52 the information relating to the notification of the notified body along with the documents mentioned in paragraph 4 of this Article and the opinion and responses referred to in paragraphs 7 and 8 of this Article. […]	**Paragraphs 4, 7 and 8:** The relevant documents mentioned in paragraph 4, and the opinion and responses referred to in paragraphs 7 and 8, are made available by means of a dedicated secure directory in CircaBC (organised by the Commission). **Paragraph 10:** The publication of notifications continues to take place via NANDO.	**Commission** (CircaBC, NANDO publication)
Article 39: *Identification*	[…] 2. The Commission shall make the list of the bodies	**Paragraph 2:** The information continues to be a made available via	**Commission** (NANDO

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number and list of notified bodies	notified under this Regulation, including the identification numbers that have been assigned to them and the conformity assessment activities as defined in this Regulation and the types of devices for which they have been notified, accessible to the public in NANDO. It shall also make this list available on the electronic system referred to in Article 52. The Commission shall ensure that the list is kept up to date.	NANDO.	publication)
Article 40: *Monitoring and re-assessment of notified bodies*	[…] 12. […] The summary of the report shall be uploaded to the electronic system referred to in Article 52.	**Paragraph 12:** Member States should upload the reports to a secure directory in CircaBC. **Note:** As soon as the functionality is available in Eudamed, the system may be used (on voluntary basis) for the upload of the reports, even before the notice of full functionality of Eudamed has been published. The Commission should make available to the public the summaries of the reports.	**Member States** (CircaBC) **Commission** (data upload, medical devices Europa website publication)
Article 42: *Changes to designations and*	[…] 7. In the event of restriction, suspension or withdrawal of a designation, the authority responsible for notified bodies shall:	**Paragraph 7:** The information in relation to requests for suspension or withdrawal of certificates is managed at national level.	**Member States** (communication)

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notifications	[…] (d) enter into the electronic system referred to in Article 52 information in relation to certificates of which it has required their suspension or withdrawal; (e) inform the competent authority for *in vitro* diagnostic medical devices of the Member State in which the manufacturer has its registered place of business through the electronic system referred to in Article 52 of the certificates for which it has required suspension or withdrawal. That competent authority shall take the appropriate measures, where necessary to avoid a potential risk to the health or safety of patients, users or others. […]	The obligation to inform the competent authority for *in vitro* diagnostic medical devices of the Member State in which the manufacturer has its registered place of business should take place by suitable communication channels (e.g. secure directory in CircaBC or e-mail). Information shared by electronic means should be encrypted whenever possible. **Note:** As soon as the functionality is available in Eudamed, the system may be used (on voluntary basis) to exchange information about requests for suspension or withdrawal of certificates, even before the notice of full functionality of Eudamed has been published.	
Article 49: *Involvement of notified bodies in conformity assessment procedures* in conj. with:	[…] 2. The notified body concerned shall, by means of the electronic system referred to in Article 52, inform the other notified bodies of any manufacturer that withdraws its application prior to the notified body's decision regarding the conformity assessment. […]	**<u>Paragraph 2:</u>** Notified bodies should upload the required information to a dedicated secure directory in CircaBC, using a pre-defined template as soon as it becomes available (organised by the Commission). **Note:** As soon as the functionality is available in Eudamed, the system may be used (on voluntary basis) to provide information on withdrawn	**Commission** (CircaBC, template) **Notified Bodies** (data upload)

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Section 4.3 of Annex VII		applications, even before the notice of full functionality of Eudamed has been published. The required information may also be made available via a national system, provided that compliance with requirements on notification of all other notified bodies is ensured.	
Article 50: *Mechanism for scrutiny of conformity assessments of class D devices*	1. A notified body shall notify the competent authorities of certificates it has granted for class D devices, with the exception of applications to supplement or renew existing certificates. Such notification shall take place through the electronic system referred to in Article 52 and shall include the instructions for use referred to in Section 20.4 of Annex I, the summary of safety and performance referred to in Article 29, the assessment report by the notified body, and, where applicable, the laboratory tests and the scientific opinion by the EU reference laboratory pursuant to the second subparagraph of Article 48(5), and where applicable the views expressed in accordance with Article 48(6) by the experts referred to in Article 106 of Regulation (EU) 2017/745. In the case of divergent views	**Paragraph 1:** Notified bodies should upload the required certificates and other mandatory information referenced in that paragraph to a CircaBC directory.	**Commission** (CircaBC) **Notified Bodies** (data upload)

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	between the notified body and the experts, a full justification shall also be included. […]		
Article 51: *Certificates of conformity*	[…] 5. The notified body shall enter in the electronic system referred to in Article 52 any information regarding certificates issued, including amendments and supplements thereto, and regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates. Such information shall be accessible to the public. […]	**Paragraph 5:** Certificates will be made available upon request or will be uploaded in the national system where required. **Note:** The functionality is available in Eudamed. The system may be used (on voluntary basis) for the upload of the certificates even before the notice of full functionality of Eudamed has been published.	**Notified Bodies**
Article 66 *Application for performance studies*	1. The sponsor of a performance study referred to in Article 58(1) and (2) shall enter and submit an application to the Member State(s) in which the performance study is to be conducted (referred to for the purposes of this Article as 'Member State concerned') accompanied by the documentation referred to in Sections 2 and 3 of Annex XIII and in Annex XIV. The application shall be submitted by means of the electronic system referred to in Article 69, which shall generate a Union-wide unique single	**Paragraph 1:** The application for performance study should take place via the respective national procedures applicable to performance studies. **Paragraphs 2 and 3:** The update and notification of the relevant information should take place via the respective national procedures applicable to performance	**Sponsors** (application) **Commission** (publication)

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	identification number for the performance study, which shall be used for all relevant communication in relation to that performance study. Within 10 days of it receiving the application, the Member State concerned shall notify the sponsor as to whether the performance study falls within the scope of this Regulation and as to whether the application dossier is complete in accordance with Chapter I of Annex XIV. 2. Within one week of any change occurring in relation to the documentation referred to in Chapter I of Annex XIV, the sponsor shall update the relevant data in the electronic system referred to in Article 69 and make that change to the documentation clearly identifiable. The Member State concerned shall be notified of the update by means of that electronic system. 3. Where the Member State concerned finds that the performance study applied for does not fall within the scope of this Regulation or that the application is not complete, it shall inform the sponsor thereof and shall set a time limit of maximum 10 days for the sponsor to comment or to complete	studies. A list of national contact points for submission should be published on the Commission website. The new performance study application form developed under the IVDR framework may be considered at national level to the extent possible.	

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	the application by means of the electronic system referred to in Article 69. […]		
Article 69 *Electronic system on performance studies*	1. The Commission shall, in collaboration with the Member States, set up, manage and maintain an electronic system: (a) to create the single identification numbers for performance studies referred to in Article 66(1); (b) to be used as an entry point for the submission of all applications or notifications for performance studies referred to in Articles 66, 70, 71, and 74 and for all other submission of data, or processing of data in this context; (c) for the exchange of information relating to performance studies in accordance with this Regulation between the Member States and between them and the Commission including the exchange of information referred to in Articles 72 and 74;	**Paragraph 1:** a. Eudamed2[7] issues a Union-wide unique single identification number ("CIV-ID") for performance studies upon submission of the required information to the system. b. This should take place via the respective national procedures relating to performance studies. c. This should be facilitated by means of ad hoc exchange, e.g. through regular teleconferences, or collaborative platforms (for example CircaBC or other online platforms). d. This should take place via the respective national procedures relating to performance studies. PS reports and the respective summary reports	**Member States** **Commission, Member States** (communication)

[7] Instructions for generating a CI/PS ID from Eudamed2 for MDR Clinical investigations and IVDR Performance studies are available following this link. In Eudamed2, there will not be a distinction between Clinical investigations and Performance studies at the level of the name (the reference generated by Eudamed2 will always start with 'CIV'). It will be therefore necessary, in order to distinguish if a Clinical investigation or a Performance Study, to specify the legislation at the beginning of the title: e.g. "IVDR – name of the performance study", as explained for MDR in the document linked.

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	(d) for information to be provided by the sponsor in accordance with Article 73, including the performance study report and its summary as required in paragraph 5 of that Article; (e) for reporting on serious adverse events and device deficiencies and related updates referred to in Article 76. […] 3. The information referred to in point (c) of paragraph 1 shall only be accessible to the Member States and the Commission. The information referred to in the other points of that paragraph shall be accessible to the public, unless, for all or parts of that information, confidentiality of the information is justified on any of the following grounds: (a) protection of personal data in accordance with Regulation (EC) No 45/2001; (b) protection of commercially confidential information, especially in the investigators brochure, in particular through taking into account the status of the conformity assessment for the device, unless there is an overriding public interest in disclosure; (c) effective supervision of the conduct of the performance study by the Member	should be published via the use of a dedicated publicly accessible CircaBC directory. The publication process should be coordinated by the MDCG to avoid duplications. e. This should take place via the respective national procedures applicable to performance studies. **<u>Paragraph 3:</u>** The accessibility of all sets of required information for the Commission, the Member States and the public, except in case a national system provides so, will be possible from the date when the Commission makes available the fully functional Eudamed.	

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	State(s) concerned. […]		
Article 70 *Performance studies regarding devices bearing the CE marking*	1. Where a performance study is to be conducted to further assess, within the scope of its intended purpose, a device which already bears the CE marking in accordance with Article 18(1), ('PMPF study'), and where the performance study would involve submitting subjects to procedures additional to those performed under the normal conditions of use of the device and those additional procedures are invasive or burdensome, the sponsor shall notify the Member States concerned at least 30 days prior to its commencement by means of the electronic system referred to in Article 69. The sponsor shall include the documentation referred to in Section 2 of Part A of Annex XIII and in Annex XIV. Points (b) to (l) and (p) of Article 58(5), and Articles 71, 72 and 73 Article 76(5) and the relevant provisions of Annexes XIII and XIV shall apply to PMPF studies. […]	**Paragraph 1:** The notification should take place via the respective national procedures applicable to performance studies.	**Sponsors** (notification)

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Article 71 *Substantial modifications to performance studies*	1. If a sponsor intends to introduce modifications to a performance study that are likely to have a substantial impact on the safety, health or rights of the subjects or on the robustness or reliability of the data generated by the study, it shall notify, within one week, by means of the electronic system referred to in Article 69 the Member State(s) in which the performance study is being or is to be conducted of the reasons for and the nature of those modifications. The sponsor shall include an updated version of the relevant documentation referred to in Annex XIV as part of the notification. Changes to the relevant documentation shall be clearly identifiable. […]	**Paragraph 1:** The notification should take place via the respective national procedures applicable to performance studies.	**Sponsors** (notification)
Article 72 *Corrective measures to be taken by Member States and information exchange between*	[…] 3. Where a Member State has taken a measure referred to in paragraph 1 of this Article or has refused a performance study, or has been notified by the sponsor of the early termination of a performance study on safety grounds, that Member State shall communicate the corresponding decision and the grounds therefor	**Paragraph 3-4:** The communication of the relevant information to other Member States and to the Commission should take place by uploading the required information to a dedicated secure directory in CircaBC.	**Member States** (CircaBC)

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Member States on performance studies	to all Member States and the Commission by means of the electronic system referred to in Article 69. 4. Where an application is withdrawn by the sponsor prior to a decision by a Member State, that information shall be made available through the electronic system referred to in Article 69 to all Member States and the Commission.		
Article 73 *Information from the sponsor at the end of a performance study or in the event of a temporary halt or early termination*	1. If the sponsor has temporarily halted a performance study or has terminated a performance study early, it shall inform within 15 days the Member State in which that performance study has been temporarily halted or terminated early, through the electronic system referred to in Article 69, of the temporary halt or early termination, providing a justification. In the event that the sponsor has temporarily halted or terminated early the performance study on safety grounds, it shall inform all Member States in which that performance study is being conducted thereof within 24 hours. […] 5. Irrespective of the outcome of the performance	**Paragraph 1:** The communication of the relevant information should take place via the respective national procedures applicable to performance studies. **Paragraph 5:** The upload of the relevant information should take place via the respective national procedures applicable to performance studies.	**Sponsors** (notification) **Member States, Commission** (CircaBC)

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	study, within one year of the end of the performance study or within three months of the early termination or temporary halt, the sponsor shall submit to the Member States in which a performance study was conducted a clinical investigation report as referred to in Section 2.3.3. of Part A of Annex XIII. The performance study report shall be accompanied by a summary presented in terms that are easily understandable to the intended user. Both the report and summary shall be submitted by the sponsor by means of the electronic system referred to in Article 69. Where, for scientific reasons, it is not possible to submit the performance study report within one year of the end of the investigation, it shall be submitted as soon as it is available. In such case, the performance study plan referred to in Section 2.3.2. of Part A of Annex XIII shall specify when the results of the performance study are going to be available, together with a justification. […] 7. The summary and the performance study report referred to in paragraph 5 of this Article shall become publicly accessible through the electronic	**Paragraph 7:** The competent authorities should share and publish the PS reports and the respective summary reports via the use of a dedicated publicly available CircaBC directory.	

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	system referred to in Article 69, at the latest when the device is registered in accordance with Article 26 and before it is placed on the market. In cases 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 accordance with Article 26 within one year of the summary and the report having been entered into the electronic system pursuant to paragraph 5 of this Article, they shall become publicly accessible at that point in time.		
Article 74 *Coordinated assessment procedure for performance studies*	1. By means of the electronic system referred to in Article 69, the sponsor of a performance study to be conducted in more than one Member State may submit, for the purpose of Article 66, a single application that, upon receipt, is transmitted electronically to all Member States in which the performance study is to be conducted. […] 8. Where the conclusion of the coordinating Member State concerning the area of coordinated assessment is that the conduct of the performance study is acceptable or acceptable subject to compliance with specific conditions,	**Paragraphs 1, 8, 11 and 12:** The procedure is mandatory as of 27 May 2029. Prior to that, the application of the procedure is voluntary as decided by the Member States willing to participate. In the absence of Eudamed, the coordinated assessment procedure will not be possible.	**Sponsors** (notification)

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	that conclusion shall be deemed to be the conclusion of all Member States concerned. Notwithstanding the first subparagraph, a Member State concerned may only disagree with the conclusion of the coordinating Member State concerning the area of coordinated assessment on the following grounds: (a) when it considers that participation in the performance study would lead to a subject receiving treatment inferior to that received in normal clinical practice in that Member State concerned; (b) infringement of national law; or (c) considerations as regards subject safety and data reliability and robustness submitted under point (b) of paragraph 4. Where one of the Member States concerned disagrees with the conclusion on the basis of the second subparagraph of this paragraph, it shall communicate its disagreement, together with a detailed justification, through the electronic system referred to in Article 69, to the Commission, to all other Member States concerned and to the sponsor. […] 11. Each Member State concerned shall notify the sponsor through the electronic system referred to		

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	in Article 69 as to whether the performance study is authorised, whether it is authorised subject to conditions, or whether authorisation has been refused. Notification shall be done by way of one single decision within five days of the transmission, pursuant to point (d) of paragraph 4, by the coordinating Member State of the final assessment report. Where an authorisation of a performance study is subject to conditions, those conditions may only be such that, by their nature, they cannot be fulfilled at the time of that authorisation. 12. Any substantial modifications as referred to in Article 71 shall be notified to the Member States concerned by means of the electronic system referred to in Article 69. Any assessment as to whether there are grounds for disagreement as referred to in the second subparagraph of paragraph 8 of this Article shall be carried out under the direction of the coordinating Member State, except for substantial modifications concerning Sections 1.13, 4.2, 4.3 and 4.4 of Chapter I of Annex XIV, which shall be assessed separately by each Member State concerned.		

Article	Provisions related to the use of Eudamed (as referred to in Art. 113 (3) (f) IVDR)	Alternative solutions to submit and/or exchange information (as required under the IVDR)	Responsible actor(s)
Article 76 *Recording and reporting of adverse events that occur during performance studies*	[…] 2. The sponsor shall report, without delay to all Member States in which the performance study is being conducted, all of the following by means of the electronic system referred to in Article 69: (a)any serious adverse event that has a causal relationship with the device, the comparator or the investigation procedure or where such causal relationship is reasonably possible; (b) any device deficiency that might have led to a serious adverse event if appropriate action had not been taken, intervention had not occurred, or circumstances had been less fortunate; (c) any new findings in relation to any event referred to in points (a) and (b). The period for reporting shall take account of the severity of the event. Where necessary to ensure timely reporting, the sponsor may submit an initial report that is incomplete followed up by a complete report. Upon request by any Member State in which the clinical investigation is being conducted, the sponsor shall provide all information referred to in paragraph 1. 3. The sponsor shall also report to the Member States in which the performance study is being	**Paragraphs 2, 3 and 4:** The reporting should take place via the respective national procedures applicable to performance studies.	**Sponsors** (notification)

Article	Provisions related to the use of Eudamed (as referred to in Art. 113 (3) (f) IVDR)	Alternative solutions to submit and/or exchange information (as required under the IVDR)	Responsible actor(s)
	conducted any event referred to in paragraph 2 of this Article that occurred in third countries in which a performance study is performed under the same clinical investigation plan as the one applying to a clinical investigation covered by this Regulation by means of the electronic system referred to in Article 69. 4. In the case of a performance study for which the sponsor has used the single application referred to in Article 74, the sponsor shall report any event as referred to in paragraph 2 of this Article by means of the electronic system referred to in Article 69. Upon receipt, this report shall be transmitted electronically to all Member States in which the performance study is being conducted. Under the direction of the coordinating Member State referred to in Article 72(2), the Member States shall coordinate their assessment of serious adverse events and device deficiencies to determine whether to modify, suspend or terminate the performance study or whether to revoke the authorisation for that performance study. This paragraph shall not affect the rights of the other Member States to perform their own		

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	evaluation and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating Member State and the Commission shall be kept informed of the outcome of any such evaluation and the adoption of any such measures. […]		
Article 81: *Periodic safety update report (PSUR)*	[…] 2. Manufacturers of class D devices shall submit PSUR by means of the electronic system referred to in Article 87 to the notified body involved in the conformity assessment of such devices in accordance with Article 48. The notified body shall review the report and add its evaluation to that electronic system with details of any action taken. Such PSUR and the evaluation by the notified body shall be made available to competent authorities through that electronic system 3. For class C devices, manufacturers shall make PSURs available to the notified body involved in the conformity assessment and, upon request, to competent authorities.	**Paragraph 2:** For class D devices, manufacturers should deliver the PSURs to the relevant notified bodies by appropriate means, such as secure email. Notified bodies should provide the PSURs and corresponding evaluations to the manufacturers and make them available upon request to the competent authority.	**Manufacturers** (notification) **Notified Bodies** (data upload notification)
Article 82:	1. Manufacturers of devices made available on the	**Paragraph 1:**	

Article	Provisions related to the use of Eudamed (as referred to in Art. 113 (3) (f) IVDR)	Alternative solutions to submit and/or exchange information (as required under the IVDR)	Responsible actor(s)
Reporting of serious incidents and field safety corrective actions	Union market, other than devices for performance studies, shall report, to the relevant competent authorities, in accordance with Articles 87(5) and (7), the following: (a) any serious incident involving devices made available on the Union market, except expected erroneous results which are clearly documented and quantified in the product information and in the technical documentation and are subject to trend reporting pursuant to Article 83; (b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country. The reports referred to in the first subparagraph shall be submitted through the electronic system referred to in Article 87. […] 9. For similar serious incidents that occur with the	Manufacturers should report serious incidents and field safety corrective actions to the respective/relevant national vigilance systems. The new MIR form has already been adapted to IVDR requirements and should be used accordingly. The current FSCA form should be used (any additional information required under the IVDR may be added to the general comments section of the form). **Paragraph 9:**	**Member States** (national vigilance system) **Manufacturers** (data submission)

Article	Provisions related to the use of Eudamed (as referred to in Art. 113 (3) (f) IVDR)	Alternative solutions to submit and/or exchange information (as required under the IVDR)	Responsible actor(s)
	same device or device type and for which the root cause has been identified or a field safety corrective action implemented or where the incidents are common and well documented, the manufacturer may provide periodic summary reports instead of individual serious incident reports, on condition that the coordinating competent authority referred to in Article 84(9), in consultation with the competent authorities referred to in point (a) and (b) of Article 87(8), has agreed with the manufacturer on the format, content and frequency of the periodic summary reporting. Where a single competent authority is referred to in points (a) and (b) of Article 87(8), the manufacturer may provide periodic summary reports following agreement with that competent authority. *(In accordance with Article 87 (1) and (8), the periodic summary reports are to be submitted via the electronic system referred to in Article 87).* […]	The current PSR Form should be used (the additional information required under the IVDR may be added to the general comments section of the form). It should be transmitted by the manufacturers via the national vigilance systems.	
Article 83: *Trend reporting*	Manufacturers shall report, by means of the electronic system referred to in Article 87, any	**Paragraph 1:** Manufacturers must submit trend reports to the	**Member States**

Article	Provisions related to the use of Eudamed (as referred to in Art. 113 (3) (f) IVDR)	Alternative solutions to submit and/or exchange information (as required under the IVDR)	Responsible actor(s)
	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 referred to in Sections 1 and 5 of Annex I and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons or of any significant increase in expected erroneous results established in comparison to the stated performance of the device as referred to in points (a) and (b) of Section 9.1 of Annex I and specified in the technical documentation and product information. […]	respective / relevant national vigilance systems. The current Trend report form should be used until its updating for IVDR compliance.	(national vigilance system) **Manufacturers** (data submission)
Article 84: *Analysis of serious incidents and field safety corrective actions*	[…] 5. The manufacturer shall provide a final report to the competent authority setting out its findings from the investigation by means of the electronic system referred to in Article 87. The report shall set out conclusions and where relevant indicate corrective actions to be taken. 7. After carrying out the evaluation in accordance with paragraph 3 of this Article, the evaluating competent authority shall, through the electronic system referred to in Article 87, inform, without delay, the other competent authorities of the	**Paragraph 5:** Manufacturers should submit the final report to the respective / relevant national vigilance system. **Paragraph 7:** Communication with other competent authorities should take place through a dedicated secure directory in CircaBC (organised by the Commission) for IVDR devices. For Legacy and older devices, the existing Eudamed2	**Member States** (national vigilance system) **Commission, Member States** (CircaBC) **Member States**

Article	Provisions related to the use of Eudamed (as referred to in Art. 113 (3) (f) IVDR)	Alternative solutions to submit and/or exchange information (as required under the IVDR)	Responsible actor(s)
	corrective action taken or envisaged by the manufacturer or required of it to minimise the risk of recurrence of the serious incident, including information on the underlying events and the outcome of its assessment. 8. […] The manufacturer shall enter the field safety notice in the electronic system referred to in Article 87 through which that notice shall be accessible to the public. […] 9. […] The coordinating competent authority shall, through the electronic system referred to in Article 87, inform the manufacturer, the other competent authorities and the Commission that it has assumed the role of coordinating competent authority.	system for NCAR should continue to apply. **Paragraph 8 (third sub-paragraph):** Manufacturers should submit the field safety notices to the respective/relevant national vigilance systems. The respective/relevant competent authorities should make these field safety notices publicly available/accessible to the public in accordance with their national legislation. **Paragraph 9:** The coordinating competent authority shall inform by email or other suitable communication channels, the other competent authorities, the manufacturer and the Commission that it has assumed the role of coordinating competent authority.	(Eudamed2) **Manufacturers** (data submission)
Article 85: *Analysis of vigilance data*	The Commission shall, in collaboration with the Member States, put in place systems and processes to actively monitor the data available in the electronic system referred to in Article 87, in order to identify trends, patterns or signals in the data that may reveal new risks or safety concerns. […]	The monitoring of data will become possible when the feature will be made available in the Eudamed Vigilance module.	

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Article 88: *Market surveillance activities*	[…] 4. The competent authorities shall prepare an annual summary of the results of their surveillance activities and make it accessible to other competent authorities by means of the electronic system referred to in Article 95. 7. The competent authority which carried out the inspection shall communicate the content of the report referred to in paragraph 6 of this Article to the economic operator that has been the subject of the inspection. Before adopting the final report, the competent authority shall give that economic operator the opportunity to submit comments. That final inspection report shall be entered in the electronic system provided for in Article 95. 8. The Member States shall review and assess the functioning of their market surveillance activities. Such reviews and assessments shall be carried out at least every four years and the results thereof shall be communicated to the other Member States and the Commission. Each Member State shall make a summary of the results accessible to the public by means of the electronic system referred to in Article 95.	**Paragraph 4:** Competent authorities should notify other relevant authorities by uploading the summary document to a dedicated secure directory in CircaBC (organised by the Commission). **Paragraph 7:** Competent authorities should make the final inspection reports available to other authorities by uploading the document to the CircaBC directory referred to under the alternative solution for paragraph 4. **Paragraph 8:** The Eudamed functionality will be available before the obligation starts to apply. Before this date, Member States may make the summaries of the results available to the public on their websites.	**Commission** (CircaBC) **Member States** (data upload, communication, publication)

Article	Provisions related to the use of Eudamed (as referred to in Art. 113 (3) (f) IVDR)	Alternative solutions to submit and/or exchange information (as required under the IVDR)	Responsible actor(s)
	[…]		
Article 90: *Procedure for dealing with devices presenting an unacceptable risk to health and safety*	[…] 2. The competent authorities shall, without delay, notify the Commission, the other Member States and, where a certificate has been issued in accordance with Article 51 for the device concerned, the notified body that issued that certificate, of the results of the evaluation and of the actions which they have required the economic operators to take, by means of the electronic system referred to in Article 95. 4. Where the economic operator as referred to in paragraph 1 does not take adequate corrective action within the period referred to in paragraph 1, the competent authorities shall take all appropriate measures to prohibit or restrict the making available of the device on their national market, to withdraw the device from that market or to recall it. The competent authorities shall notify the Commission, the other Member States and the notified body referred to in paragraph 2 of this Article, without delay, of those measures, by	**Paragraphs 2, 4 and 6:** Competent authorities should notify other relevant parties by means of e-mail or by using other suitable communication channels, using a pre-defined template. Information shared by electronic means should be encrypted whenever possible and deemed necessary.	**Member States** (communication)

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	means of the electronic system referred to in Article 95. 6. Member States other than the Member State initiating the procedure shall, without delay, inform the Commission and the other Member States, by means of the electronic system referred to in Article 95, of any additional relevant information at their disposal relating to the non-compliance of the device concerned and of any measures adopted by them in relation to the device concerned. In the event of disagreement with the notified national measure, they shall, without delay, inform the Commission and the other Member States of their objections, by means of the electronic system referred to in Article 95. […]		
Article 92: *Other non-compliance*	[…] 2. Where the economic operator does not bring the non-compliance to an end within the period referred to in paragraph 1 of this Article, the Member State concerned shall, without delay, take all appropriate measures to restrict or	**Paragraph 2:** The Member State should notify the Commission and other Member States by means of e-mail, using a pre-defined template. Information shared by electronic means should be encrypted whenever possible and deemed necessary.	**Member States** (communication)

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	prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the market. That Member State shall inform the Commission and the other Member States, without delay, of those measures, by means of the electronic system referred to in Article 95. […]		
Article 93: *Preventive health protection measures*	[…] 2. The Member State referred to in paragraph 1 shall immediately notify the Commission and all other Member States, giving the reasons for its decision, by means of the electronic system referred to in Article 95.	**Paragraph 2:** The Member State should notify the Commission and other Member States by means of e-mail, using a pre-defined template. The information shared by electronic means should be encrypted whenever possible and deemed necessary.	**Member States** (communication)
Article 94: *Good administrative practice*	[…] 4. Where a measure adopted pursuant to Articles 90 to 93 concerns a device for which a notified body has been involved in the conformity assessment, the competent authorities shall by means of the electronic system referred to in Article 95 inform the relevant notified body and the authority responsible for the notified body of the measure taken.	**Paragraph 4:** Competent authorities should notify the relevant notified bodies and responsible authorities by means of e-mail. The information shared by electronic means should be encrypted whenever possible and deemed necessary.	**Member States** (communication)

Article	Provisions related to the use of Eudamed (as referred to in Art. 113 (3) (f) IVDR)	Alternative solutions to submit and/or exchange information (as required under the IVDR)	Responsible actor(s)
Article 110: *Transitional provisions*	[…] 3. However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in that Directive.	**Paragraph 3:** The alternative technical solutions set out in this document should also apply to legacy devices where appropriate, taking into account the availability of the respective Eudamed modules. The registration of certificates issued in accordance with the Directives should take place in Eudamed2.	**Member States** (certificate registration, Eudamed2)