MDCG 2021-1 Rev.1

Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional

May 2021

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

MDCG 2021-1 Rev.1 changes	
Third paragraph	Sentence deleted: *"Parties should also note that, in principle and unless otherwise concluded by the MDCG, the reporting obligations with regard to EUDAMED apply to all information generated and collected under the MDR from its date of application (e.g. UDI, certificates) and therefore must be carried out as soon as EUDAMED becomes fully functional"*

INTRODUCTION

Article 33 of Regulation (EU) 2017/745 on medical devices[1] (MDR) requires the Commission to set up a European database on medical devices ('EUDAMED'). According to Article 33(2) of the MDR, Eudamed will be composed of six different electronic systems (so called 'modules'), which facilitate the collation and processing of information under the MDR 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, vigilance and market surveillance as well as post-market surveillance.

On 30 October 2019, the Commission published a notice[2] by which it concluded that the full functionality of EUDAMED requires the availability and full operation of all six modules, both individually and jointly. The notice foresees the launch of EUDAMED for May 2022, which correlates with the date of application of Regulation (EU) 2017/746 on in vitro diagnostic medical devices[3] (IVDR). In

[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] Available at: https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/eudamed_en.
[3] 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, OJ L 117, 5.5.2017, p. 176–332.

this regard, it is important to note that the official launch of EUDAMED in May 2022 does not affect the date of application of the MDR on 26 May 2021.

Article 123(3)(d) MDR addresses the possibility that EUDAMED is not fully functional on the date of application of the MDR (26 May 2021). Accordingly, the obligations and requirements in the MDR 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) – notice of full functionality of Eudamed. Until EUDAMED is fully functional, the MDR stipulates that the corresponding provisions of Directives 90/385/EEC[4] and 93/42/EEC[5] shall continue to apply for the purpose of meeting the obligations laid down in the provisions of Article 123(3)(d) regarding the exchange of information.

In addition, Article 123(3)(e) MDR clarifies that Article 29(4) MDR on the registration of devices, and Article 56(5) MDR 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.

Article 122 is outside scope of this guidance.

SCOPE

This document provides guidance to Member States and other relevant parties on the application of certain MDR 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 MDR 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 Directives 90/385/EEC and 93/42/EEC. In doing so, this guidance takes into account the decision of the Medical Device Coordination Group in its meeting of 12 March 2020 where the group agreed that the Commission makes available to Member

[4] Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, OJ L 189, 20.7.1990, p. 17–36.
[5] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ L 169, 12.7.1993, p. 1–43.

States each EUDAMED module as soon as it is operational. This approach also has an impact on the means by which relevant information collected under the MDR will be made available to the public, which shall take place on a gradual basis.

The proposed practices and solutions set out in this document do not affect the general obligations of the parties to comply with the requirements under the MDR, including those contained in the provisions referred to in Article 123(3) letters (d) and (e) MDR.

Whenever this guidance makes reference to CircaBC[6] 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.[7]

Article	Provisions related to the use of EUDAMED (as referred to in Art. 123(3)(d) MDR)	Alternative solutions to submit and/or exchange information (as required under the MDR)	Responsible actor(s)
Article 29: *Registration of devices*	1. Before placing a device, other than a custom-made device, on the market, the manufacturer shall, in accordance with the rules of the issuing entity referred to in Article 27(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.	**Paragraphs 1-4:** As soon as the functionality is available in Eudamed, the system may be used 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	**Manufacturers** (device registration, assignment and labelling)

[6] https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp
[7] MDCG 2020-15.

	2. Before placing on the market a system or procedure pack pursuant to Article 22(1) and (3), that is not a custom- made device, the natural or legal person responsible shall assign to the system or procedure pack, in compliance with the rules of the issuing entity, a Basic UDI-DI 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 system or procedure pack. 3. For devices that are the subject of a conformity assessment as referred to in Article 52(3) and in the second and third subparagraphs of Article 52(4), 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 Chapter I 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 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.	product registration schemes. Manufacturers should note that the obligation of UDI assignment (Basic UDI and UDI-DI) to a device applies from 26 May 2021 (Art. 27(3) MDR). Labelling requirements apply gradually, starting from 26 May 2021 (Art. 123(3)(f) MDR).	

	4. Before placing a device on the market, other than a custom-made device, 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 shall thereafter keep the information updated.		
Article 31: *Registration of manufacturers, authorised representatives and importers*	1. Before placing a device, other than a custom-made 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 52, 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 registration number ('SRN') from the electronic system referred to in Article 30 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 29. […]	**<u>Paragraphs 1-3:</u>** As soon as the functionality is available in Eudamed, the system may be used 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)

Article 32: *Summary of safety and clinical performance*	1. For implantable devices and for class III devices, other than custom-made or investigational devices, the manufacturer shall draw up a summary of safety and clinical performance. The summary of safety and clinical 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 clinical performance shall be part of the documentation to be submitted to the notified body involved in the conformity assessment pursuant to Article 52 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 label or instructions for use where the summary is available. 2. The summary of safety and clinical 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; […]	**Paragraphs 1:** The SSCP 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. As soon as the functionality is available in Eudamed, the system may be used for the upload of the SSCP even before the notice of full functionality of Eudamed has been published. **Paragraph 2:** Please refer to alternative solution for Art. 31.	**Manufacturers** **Notified Bodies**
Article 33: *European database on medical*	[…] 2. Eudamed shall include the following electronic systems: (a) the electronic system for registration of	**Paragraphs 2 and 4:** The submission of the different sets of required information will become possible on a voluntary basis from the date when the Commission makes	

devices	devices referred to in Article 29(4); (b) the UDI-database referred to in Article 28; (c) the electronic system on registration of economic operators referred to in Article 30; (d) the electronic system on notified bodies and on certificates referred to in Article 57; (e) the electronic system on clinical investigations referred to in Article 73; (f) the electronic system on vigilance and post-market surveillance referred to in Article 92; (g) the electronic system on market surveillance referred to in Article 100. […] 4. The data shall be entered into Eudamed by the Member States, notified bodies, economic operators and sponsors as specified in the provisions on the electronic systems referred to in paragraph 2. The Commission shall provide for technical and administrative support to users of Eudamed. […]	available the respective EUDAMED module (see introductory text).	-
Article 40: *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 57.	**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 42: *Designation and notification procedure*	[…] 10. When publishing the notification in NANDO, the Commission shall also add to the electronic system referred to in Article 57 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 43: *Identification number and list of notified bodies*	[…] 2. The Commission shall make the list of the 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 57. The Commission shall ensure that the list is kept up to date.	**Paragraph 2:** The information continues to be a made available via NANDO.	**Commission** (NANDO publication)
Article 44: *Monitoring and re-assessment of notified bodies*	[…] 12. […] The summary of the report shall be uploaded to the electronic system referred to in Article 57.	**Paragraph 12:** Member States should upload the reports to the secure directory in CircaBC referred to under the alternative solution for Article 42. 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 46: *Changes to designations and notifications*	[…] 7. In the event of restriction, suspension or withdrawal of a designation, the authority responsible for notified bodies shall: […] (d) enter into the electronic system referred to in Article 57 information in relation to certificates of which it has required their suspension or withdrawal; (e) inform the competent authority for medical devices of the Member State in which the manufacturer has its registered place of business through the electronic system referred to in Article 57 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. […]	**Paragraph 7:** The information in relation to requests for suspension or withdrawal of certificates is managed at national level. The obligation to inform the competent authority for 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.	**Member States** (communication)
Article 53: *Involvement of notified bodies in conformity assessment procedures* in conj. with: **Section 4.3 of Annex VII**	[…] 2. The notified body concerned shall, by means of the electronic system referred to in Article 57, inform the other notified bodies of any manufacturer that withdraws its application prior to the notified body's decision regarding the conformity assessment. […]	**Paragraph 2:** 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). 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.	**Commission** (CircaBC, template) **Notified Bodies** (data upload)

Article 54: *Clinical evaluation consultation procedure for certain class III and class IIb devices*	[…] 3. The notified body shall notify the competent authorities, the authority responsible for notified bodies and the Commission through the electronic system referred to in Article 57 of whether or not the procedure referred to in paragraph 1 of this Article is to be applied. That notification shall be accompanied by the clinical evaluation assessment report. […]	**Paragraph 3:** Notified bodies should notify the relevant parties by uploading 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 on expert panels:** The Commission will provide and manage a technical platform related to the functioning of expert panels. Guidance on this technical solution will be provided separately to relevant parties.	**Commission** (CircaBC, template, expert panel platform) **Notified Bodies** (data upload)
Article 55: *Mechanism for scrutiny of conformity assessments of certain class III and class IIb devices*	1. A notified body shall notify the competent authorities of certificates it has granted to devices for which the conformity assessment has been performed pursuant to Article 54(1). Such notification shall take place through the electronic system referred to in Article 57 and shall include the summary of safety and clinical performance pursuant to Article 32, the assessment report by the notified body, the instructions for use referred to in Section 23.4 of Annex I, and, where applicable, the scientific opinion of the expert panels referred to in Section 5.1 of Annex IX or Section 6 of Annex X, as applicable. In the case of divergent views between the notified body and the expert panels, a full justification shall also be included. […]	**Paragraph 1:** Notified bodies should upload the required certificates and other mandatory information referenced in that paragraph to the CircaBC directory referred to under the alternative solution for Article 54.	**Commission** (CircaBC) **Notified Bodies** (data upload)

Article 56: *Certificates of conformity*	[…] 5. The notified body shall enter in the electronic system referred to in Article 57 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:** As soon as the functionality is available in Eudamed, the system may be used for the upload of the certificates even before the notice of full functionality of Eudamed has been published.	**Notified Bodies**
Article 70 *Application for clinical investigations*	1. The sponsor of a clinical investigation shall submit an application to the Member State(s) in which the clinical investigation is to be conducted (referred to for the purposes of this Article as 'Member State concerned') accompanied by the documentation referred to in Chapter II of Annex XV. The application shall be submitted by means of the electronic system referred to in Article 73, which shall generate a Union-wide unique single identification number for the clinical investigation, which shall be used for all relevant communication in relation to that clinical investigation. Within 10 days of it receiving the application, the Member State concerned shall notify the sponsor as to whether the clinical investigation falls within the scope of this Regulation and as to whether the application dossier is complete in accordance with Chapter II of Annex XV. 2. Within one week of any change occurring in	**Paragraph 1:** The application for clinical investigations should take place via the respective national procedures applicable to clinical investigations. **Paragraph 2:** Non-substantial modifications will be notified to the Member State before its implementation, via respective national procedures, unless otherwise defined by the Member State. **Paragraphs 2 and 3:** The notification of the relevant information should take place via the respective national procedures applicable to clinical investigations. A list of national contact points for submission should be published on the Commission website. The new clinical investigation application form developed under the MDR framework may be considered at national level to the extent possible.	**Sponsors** (application) **Commission** (publication)

	relation to the documentation referred to in Chapter II of Annex XV, the sponsor shall update the relevant data in the electronic system referred to in Article 73 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 clinical investigation applied for does not fall within the scope of this Regulation or that the application dossier 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 the application by means of the electronic system referred to in Article 73. […]		
Article 73 *Electronic system on clinical investigations*	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 clinical investigations referred to in Article 70(1); (b) to be used as an entry point for the submission of all applications or notifications for clinical investigations	**Paragraph 1:** a. Eudamed2[8] issues a Union-wide unique single identification number (the 'CIV-ID') for clinical investigations upon submission of the required information to the system (continuation of current MDD practice)[9]. b. This should take place via the respective national procedures applicable to clinical	**Member States** (Eudamed2, communication)

[8] Eudamed2 will not be subject to any modifications.
[9] "MDR" should be added at the beginning of the CI title, indicating the sponsor and investigational devices, without risk class. Operational guidance will be issued by MDCG CIE.

	referred to in Articles 70, 74, 75 and 78 and for all other submission of data, or processing of data in this context; (c) for the exchange of information relating to clinical investigations in accordance with this Regulation between the Member States and between them and the Commission including the exchange of information referred to in Articles 70 and 76; (d) for information to be provided by the sponsor in accordance with Article 77, including the clinical investigation 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 80. […] 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	investigations. 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 applicable to clinical investigations. CI reports and the respective summary reports 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 clinical investigations and as described in the MDCG Guidance on safety reporting in clinical investigations.[10] **<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 respective EUDAMED module or, alternatively, when EUDAMED becomes fully functional.	**Commission, Member States** (communication)

[10] MDCG 2020-10/1 Safety reporting in clinical investigations of medical devices under the Regulation (EU) 2017/745.

	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 clinical investigation by the Member State(s) concerned. […]		
Article 74 *Clinical investigations regarding devices bearing the CE marking*	1. Where a clinical investigation 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 20(1), ('PMCF investigation'), and where the investigation 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 73. The sponsor shall include the documentation referred to in Chapter II of Annex XV as part of the notification. Points (b) to (k) and (m) of Article 62(4), Article 75, Article 76, Article 77, Article 80(5) and the relevant provisions of Annex XV shall apply to PMCF investigations. […]	**Paragraph 1:** The notification of the relevant information should take place via the respective national procedures applicable to clinical investigations.	**Sponsors** (notification)
Article 75	1. If a sponsor intends to introduce modifications	**Paragraph 1:**	

Substantial modifications to clinical investigations	to a clinical investigation 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 clinical data generated by the investigation, it shall notify, within one week, by means of the electronic system referred to in Article 73 the Member State(s) in which the clinical investigation 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 Chapter II of Annex XV as part of the notification. Changes to the relevant documentation shall be clearly identifiable. […]	The notification of the relevant information should take place via the respective national procedures applicable to clinical investigations.	**Sponsors** (notification)
Article 76 *Corrective measures to be taken by Member States and information exchange between Member States*	[…] 3. Where a Member State has taken a measure referred to in paragraph 1 of this Article or has refused a clinical investigation, or has been notified by the sponsor of the early termination of a clinical investigation on safety grounds, that Member State shall communicate the corresponding decision and the grounds therefor to all Member States and the Commission by means of the electronic system referred to in Article 73. 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	**<u>Paragraph 3-4:</u>** 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, using a pre-defined template once available.	**Member States** (CircaBC)

	Article 73 to all Member States and the Commission.		
Article 77 *Information from the sponsor at the end of a clinical investigation or in the event of a temporary halt or early termination*	1. If the sponsor has temporarily halted a clinical investigation or has terminated a clinical investigation early, it shall inform within 15 days the Member State in which that clinical investigation has been temporarily halted or terminated early, through the electronic system referred to in Article 73, of the temporary halt or early termination, providing a justification. In the event that the sponsor has temporarily halted or terminated early the clinical investigation on safety grounds, it shall inform all Member States in which that clinical investigation is being conducted thereof within 24 hours. […] 5. Irrespective of the outcome of the clinical investigation, within one year of the end of the clinical investigation or within three months of the early termination or temporary halt, the sponsor shall submit to the Member States in which a clinical investigation was conducted a clinical investigation report as referred to in Section 2.8 of Chapter I and Section 7 of Chapter III of Annex XV. The clinical investigation 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 73. Where, for scientific	**Paragraph 1:** The communication of the relevant information should take place via the respective national procedures applicable to clinical investigations. **Paragraph 5:** The upload of the relevant information should take place via the respective national procedures applicable to clinical investigations. **Paragraph 7:** CI reports and the respective summary reports should be shared and published via the use of a dedicated publicly available CircaBC directory. See also guidance on Article 73(1)(d) above.	**Sponsors** (notification) **Commission** (CircaBC)

	reasons, it is not possible to submit the clinical investigation report within one year of the end of the investigation, it shall be submitted as soon as it is available. In such case, the clinical investigation plan referred to in Section 3 of Chapter II of Annex XV shall specify when the results of the clinical investigation are going to be available, together with a justification. […] 7. The summary and the clinical investigation report referred to in paragraph 5 of this Article shall become publicly accessible through the electronic system referred to in Article 73, at the latest when the device is registered in accordance with Article 29 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 29 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 78 *Coordinated assessment procedure for clinical investigations*	1. By means of the electronic system referred to in Article 73, the sponsor of a clinical investigation to be conducted in more than one Member State may submit, for the purpose of Article 70, a single application that, upon receipt, is transmitted electronically to all	**Paragraphs 1, 8, 11 and 12:** The procedure is mandatory as of 27 May 2027. Prior to that, the application of the procedure is voluntary as decided by the Member States willing to participate. The MDCG may provide further guidance on the	**Sponsors** (notification)

	Member States in which the clinical investigation 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 clinical investigation is acceptable or acceptable subject to compliance with specific conditions, 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 clinical investigation 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 73, to the Commission, to all other Member States concerned and to the sponsor.	voluntary procedure, if deemed necessary.	

	[…] 11. Each Member State concerned shall notify the sponsor through the electronic system referred to in Article 73 as to whether the clinical investigation 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 clinical investigation 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 75 shall be notified to the Member States concerned by means of the electronic system referred to in Article 73. 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, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XV, which shall be assessed separately by each Member State concerned.		
Article 80 *Recording and*	[…] 2. The sponsor shall report, without delay to all	**Paragraphs 2, 3 and 4:** The reporting should take place via the respective	**Sponsors**

reporting of adverse events that occur during clinical investigations	Member States in which the clinical investigation is being conducted, all of the following by means of the electronic system referred to in Article 73: (a)any serious adverse event that has a causal relationship with the investigational 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 clinical investigation is being conducted any event referred to in paragraph 2 of this Article that occurred in third countries in which a clinical investigation is performed under the same clinical	national procedures applicable to clinical investigations and in accordance with the MDCG Guidance on safety reporting in clinical investigations of medical devices under the Regulation (EU) 2017/745.[11]	(notification)

[11] MDCG 2020-10/1 and MDCG 2020-10/2.

	investigation plan as the one applying to a clinical investigation covered by this Regulation by means of the electronic system referred to in Article 73. 4. In the case of a clinical investigation for which the sponsor has used the single application referred to in Article 78, 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 73. Upon receipt, this report shall be transmitted electronically to all Member States in which the clinical investigation is being conducted. Under the direction of the coordinating Member State referred to in Article 78(2), the Member States shall 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. This paragraph shall not affect the rights of the other Member States to perform their own 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 86: *Periodic safety update report (PSUR)*	[…] 2. For class III devices or implantable devices, manufacturers shall submit PSURs by means of the electronic system referred to in Article 92 to the notified body involved in the conformity assessment in accordance with Article 52. The notified body shall review the report and add its evaluation to that electronic system with details of any action taken. Such PSURs and the evaluation by the notified body shall be made available to competent authorities through that electronic system. 3. For devices other than those referred to in paragraph 2, manufacturers shall make PSURs available to the notified body involved in the conformity assessment and, upon request, to competent authorities.	**Paragraph 2:** For class III devices and for classes IIa, and IIb implantable devices, manufacturers should deliver the PSURs to the relevant notified bodies by appropriate means. 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 87: *Reporting of serious incidents and field safety corrective actions*	1. Manufacturers of devices made available on the Union market, other than investigational devices, shall report, to the relevant competent authorities, in accordance with Articles 92(5) and (7), the following: (a) any serious incident involving devices made available on the Union market, except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting pursuant to Article 88; (b) any field safety corrective action in respect of devices made available on the Union market, including any field safety	**Paragraph 1:** 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 MDR requirements and should be used accordingly. The current FSCA form should be used (the additional information required under the MDR may be added to the general comments section of the form).	**Member States** (national vigilance system) **Manufacturers** (data submission)

	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 92. […] 9. For similar serious incidents that occur with the 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 89(9), in consultation with the competent authorities referred to in point (a) of Article 92(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 92(8), the manufacturer may provide periodic summary reports following agreement with that competent authority. The reports referred to in the ninth subparagraph shall be submitted through the electronic system referred to in Article 92.	**Paragraph 9:** The current PSR Form should be used (the additional information required under the MDR may be added to the general comments section of the form). It should be transmitted by the manufacturers via the national vigilance systems.	

	[…]		
Article 88: *Trend reporting*	1. Manufacturers shall report, by means of the electronic system referred to in Article 92, 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 referred to in Sections 1 and 5 of Annex I and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits. […]	**Paragraph 1:** Manufacturers must submit trend reports to the respective / relevant national vigilance systems. The current Trend report form should be used until its updating for MDR compliance.	**Member States** (national vigilance system) **Manufacturers** (data submission)
Article 89: *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 92. 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 92, inform, without delay, the other competent authorities of the 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	**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 MDR devices. For Legacy and older devices, the existing Eudamed2 system for NCAR should continue to apply.	**Member States** (national vigilance system) **Commission, Member States** (CircaBC) **Member States** (Eudamed2) **Manufacturers**

	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 92 through which that notice shall be accessible to the public. […] 9. […] The coordinating competent authority shall, through the electronic system referred to in Article 92, inform the manufacturer, the other competent authorities and the Commission that it has assumed the role of coordinating competent authority.	**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.	(data submission)
Article 90: *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 92, 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 from the date when EUDAMED Vigilance module is made available.	
Article 93: *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 100.	**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).	**Commission** (CircaBC) **Member States** (data upload, communication,

	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 100. 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 100. […]	**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.	publication)
Article 95: *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 56 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	**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 (once available). Information shared by electronic means should be encrypted whenever possible and deemed necessary.	**Member States** (communication)

	means of the electronic system referred to in Article 100. 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 means of the electronic system referred to in Article 100. 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 100, 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 100. […]		

Article 97: *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 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 100. […]	**Paragraph 2:** The Member State should notify the Commission and other Member States by means of e-mail, using a pre-defined template (once available). Information shared by electronic means should be encrypted whenever possible and deemed necessary.	**Member States** (communication)
Article 98: *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 100.	**Paragraph 2:** The Member State should notify the Commission and other Member States by means of e-mail, using a pre-defined template (once available). The information shared by electronic means should be encrypted whenever possible and deemed necessary.	**Member States** (communication)
Article 99: *Good administrative practice*	[…] 4. Where a measure adopted pursuant to Articles 95 to 98 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 100 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 120: *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 those Directives.	**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)