Manufacturer incident report (MIR) v7.3.1 Helptext for reporting Serious Incidents (MDR/IVDR)

1. MIR Helptext
2. Rules
3. EMDN Coding & IMDRF Adverse Event Terminology
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Please note:

- ❖ It is important to strictly follow the numbering of the document (top-down) when filling-up sections in the MIR form.
- ❖ Free text fields are limited to 4000 characters (approximately 1 A4).
- ❖ Adobe Acrobat Professional is necessary for signing and XML data import/export.

MIR Helptext

Section		Help text	Mandatory properties					Comments
			Combined initial & final	Initial	Follow Up	Final (Reportable incident)	Final (Non-reportable incident)	
1.	**Administrative information**							
1.1	**Responsible competent authority in which country the incident occurred**							
a	Name of receiving national competent authority (NCA)	NCA to which the report is being sent.	Y	Y	Y	Y	Y	List is available here: https://health.ec.europa.eu/medical-devices-sector/new-regulations/contacts_en under Vigilance contact points.
b	EUDAMED Number of NCA	Unique EUDAMED number of NCA (could be auto filled/selected once EUDAMED available).	N	N	N	N	N	Will be mandatory as soon as available in EUDAMED.
c	Reference number assigned by NCA for this incident	The reference number of the NCA for this incident. This is a mandatory field when reference number is provided by the NCA. If no reference number is provided by the NCA, please add 'Unknown' in the follow-up and final reports.	(N)	N	Y	Y	Y	
d	Reference number assigned by EUDAMED for this incident	The reference number assigned by EUDAMED for this incident (after upload/entering incident into EUDAMED).	N	N	N	N	N	Will be mandatory as soon as available in EUDAMED.
1.2	**Date, type, and classification of incident report**							
a	Date of report submission	Date when you submit the report - The predefined date format is: YYYY-MM-DD.	Y	Y	Y	Y	Y	
b	Date of incident	Date when incident happened. - if incident date is unknown, please enter a date range when you think the incident occurred. - If this incident is a result of a literature report, please enter a date range similar to the range of the report.	Y	Y	Y	Y	Y	Please note: - In case the specific date is known you only have to enter it once into the first field. The same date is automatically entered into the second field. - In case of a timespan, you need to adjust the second field accordingly.
c	Manufacturer awareness date of the incident	The 'manufacturer awareness date' is the date, when the first employee or representative of the manufacturer's organisation receives information (e.g., a complaint) regarding the incident.	Y	Y	Y	Y	Y	Please note: - Please refer to the guidance document MDCG 2023-3: *Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices* for further information on what is considered as the 'manufacturer awareness date'.
d	Manufacturer awareness date of reportability	In this field, the manufacturer should insert the date in which it received the information that determined that the incident is reportable and thus met the criteria of a incident.	Y	Y	Y	Y	N	Please note: - Please refer to the guidance document MDCG 2023-3: *Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices* for further information on what is considered as the 'manufacturer awareness date of reportability'.
e	Type of Report	Initial Report - Choose this for your first report on a particular incident if your investigation is not complete and a combined report cannot be submitted. It may be initiated under the Vigilance system or may stem from a User incident Report notified to you by the relevant CA. Follow-up report - Choose this to provide additional/interim information during your investigation. You can submit more than one follow-up report for each incident. Note this option is only available once you have submitted an initial	Y	Y	Y	Y	Y	Please note: - a report submitted as type "Final (reportable incident)" fulfils the definition of a 'serious incident' according to article 2 MDR/IVDR and the reporting criteria for a serious incident as defined in article 87(1) MDR, article 82(1) IVDR". - MDR art. 87(3), IVDR art. 82 (3); Manufacturers shall report any serious incident immediately after they have established the causal relationship between that serious incident and their device or that such causal relationship is reasonably

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		report. Combined initial & final - Choose this if you have the details of the initial and final report within the initial timeframe for reporting. Note that this option is not available once you have submitted an initial report. Final (Reportable incident)- This is your formal statement of the outcome of your investigation, including any actions proposed or taken. It is recognized that a further 'Final' report may be necessary in circumstances where additional information only becomes available at a later stage. Please indicate which information has changed in case an updated final report is submitted. Note this option is only available once you have submitted an initial report. Final (Non-reportable incident)- This is to be used for cases where the manufacturer has submitted a MIR to the relevant competent authority but establishes through its investigation that the criteria for a serious incident were not met OR for cases where the manufacturer has received a report of a potentially serious incident from the competent authorities (Article 87(11) MDR/Article 82(11) IVDR) but establishes within the specified timelines that the requirements for a serious incident are not fulfilled. For further information, please refer to the MDCG 2023-3 Rev. 2 (Q16). By selecting this option, the only mandatory field in section 4 is 4.2b.. It is possible to send an update at any stage to each type of reports except for the initial report e.g. update to the final report.						possible and not later than 15 days after they become aware of the serious incident. - Reporting timelines: For details on the interpretation of the reporting timelines for the different classes of incidents, please refer to the guidance document: MDCG 2023-3: *Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices.*
f	In case of initial and follow-up reports, please indicate the expected date of next report	The date by which you expect to be able to submit your next report on this event. This may be either a Follow-Up or Final report.	N	Y	Y	N	N	
g	Classification of serious incident	Please classify the serious incident according with the following definitions: **Serious public health threat:** An incident which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time. **Death:** A incident of death must be reported as soon as a causal relationship has been established with the device but not later than 10 days from the awareness date. An incident of Death cannot be exempted from reporting when expected side effects have also been reported and it is reasonable possible that these expected side effects contributed to the patient outcome of death. **An unanticipated serious deterioration in state of health:** A deterioration in state of health is considered UNANTICIPATED if the condition leading to the event was not considered in a risk analysis. NOTE: Documented evidence in the design file is needed that such analysis was used to reduce the risk to an acceptable level, or that this risk is well known by the intended USER. **All other reportable incidents:** These are incidents which did not involve a death (where a causal relationship has been determined) and which **were not unanticipated** but:	Y	Y	Y	Y	N	Please note: - a report submitted as "All other reportable incidents:" fulfils the definition of a 'serious incident' according to article 2 MDR/IVDR and the reporting criteria for a serious incident as defined in article 87(1) MDR, article 82(1) IVDR". - Reporting timelines: For details on the interpretation of the reporting timelines for the different classes of incidents, please refer to the guidance document: MDCG 2023-3: *Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices.*

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		1. led, might have led, or might lead to a serious deterioration in the state of health of a patient, user or other person. 2. and the event is linked or might have been linked to device malfunction, deterioration in the characteristics or performance of the device or an inadequacy in the information supplied by the manufacturer.						
1.3	**Submitter information**							
1.3.1	**Submitter of the report**							
a	Submitter of report	Who is submitting the report.	Y	Y	Y	Y	Y	Please note: - Adobe Acrobat Professional is necessary for signing and XML data import/export. - Depending on the type of submitter selected fields in section 1.3.2 (MFR), 1.3.3 (AR) or 1.3.4 (submitter) become mandatory. - It is important to strictly follow the lines order **(top-down)** when filling-up sections in the MIR form.
b	Manufacturer's reference number for this incident	The reference number assigned by the manufacturer. The Manufacturer's reference number must be unique.	Y	Y	Y	Y	Y	
c	If this incident involves multiple devices from the same manufacturer, please list the respective reference numbers of the other MIR forms you have submitted	If other devices were involved in the incident, you must send a separate MIR form for each device. List the reference numbers of the NCA, EUDAMED and manufacturer here (As each suspected device will have its own report as opposed to section 2.6 where only accessories associated to the suspected device(s) are listed). Please use a semi colon to separate multiple values 1.3.c, 2.6: If you are certain of the device that caused the incident, then this device is what should be reported on the form. List any associated accessories in: - 2.6a, which could be from a different manufacturer if known. - 2.6b, for any other devices (which could also be from a different manufacturer if known). This will indicate to the CA that those other manufacturers should also submit a MIR.	N	N	N	N	N	Please note: - 1 MIR is linked to 1 device. - Separate MIRs should be submitted by the manufacturer when several devices and their accessories are involved in a incident (one for each device). - If the manufacturer is confident that some devices present cannot be the cause of the incident, it will not be required to submit a separate MIR for each device, but will specify them in section 2.6 b. However, if the NCA has doubts about the conclusion made by the manufacturer, submitting an additional MIR for other devices specified in section 2.6. might be required. - Accessories and systems/procedure packs in the context of future EUDAMED. It is not possible to submit a MIR for an accessory or a systems/procedure pack that is not a device in its own right, only a manufacturer of a device or its authorised representative if applicable (and their sub-contractors acting on their behalf) may submit a MIR, not a system/procedure pack producer.
d	If this incident is covered under a FSCA, please provide the relevant numbers:	Please add the relevant FSCA number when evidence confirms that the incident observed is associated with the FSCA (i.e., upon manufacturer investigation). NCA's local FSCA reference: The NCA reference number assigned to the FSCA that this incident covers. EUDAMED's FSCA reference number: Future EUDAMED reference number assigned to the FSCA that this incident covers. If the FSCA sent to the NCA contained multiple issues, the NCA may assign a unique number to each issue. If this incident in this report is related to one of those issues, list the unique number assigned by the NCA for that issue in the field "NCA's local FSCA reference" Please use a semi colon to separate multiple values.	N	N	N	N	N	

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e	Periodic Summary Report (PSR) ID	Please quote the unique PSR-ID (determined by the Manufacturer) for the incident if it is reportable under PSR. Please use a semi colon to separate multiple values.	N	N	N	N	N	Please note: - A new methodology for PSR submission is currently under development for reporting of PSR in EUDAMED. This field is here as a placeholder to facilitate this new method of submission.
f	The incident occurred within a PMCF/PMPF investigation	If the incident occurred within a PMCF/ PMPF investigation; please provide the EUDAMED ID of that PMCF/PMPF investigation.	N	N	N	N	N	Please note: - The word 'studies' is generally used for PMCF/PMPF however the MDR refers to this as 'investigation' and IVDR as 'studies'.
1.3.2	**Manufacturer information**							
a	Manufacturer Organisation name	The name of the Manufacturer for the device involved in this incident.	Y	Y	Y	Y	Y	
b	Single registration number	SRN is the unique identifier which will be the unique identifier of actors in the future EUDAMED. When an SRN is available, an SRN field will be completed and will pre-populate in EUDAMED the manufacturer details, including the Manufacturer's name.	Y	Y	Y	Y	Y	Please note: - The use of an SRN is not mandatory before EUDAMED becomes fully functional. If the manufacturer has not obtained an SRN yet, "Unknown" can be filled in the text field. - SRN of Manufacturer is different from the AR SRN number. - Need to obtain an SRN before submitted the MIR or uploading the XML file in future EUDAMED.
c	Contact's first name	First name of the manufacturer contact person.	Y	Y	Y	Y	Y	Please note: - Information in c, d, e and f will not be auto populated when EUDAMED becomes mandatory. These fields will be editable so can be overwritten/updated.
d	Contact's last name	Last name of the manufacturer contact person.	Y	Y	Y	Y	Y	Information in c, d, e, f will not be auto populated when in EUDAMED. These fields will be editable so can be overwritten/updated. If there is an Authorised Representative, the AR will be the preliminary contact for CA when manufacturer is outside Europe. Please also include a manufacturer contact (as well as the Authorised Representative.)
e	Email	E-mail of the manufacturer contact person.	Y	Y	Y	Y	Y	Information in c, d, e, f will not be auto populated when in EUDAMED. These fields will be editable so can be overwritten/updated. If there is an Authorised Representative, the AR will be the preliminary contact for CA when manufacturer is outside Europe. Please also include a manufacturer contact (as well as the Authorised Representative.)
f	Phone	Telephone number of the manufacturer contact person.	Y	Y	Y	Y	Y	Information in c, d, e, f will not be auto populated when in EUDAMED. These fields will be editable so can be overwritten/updated. If there is an Authorised Representative, the AR will be the preliminary contact for CA when manufacturer is outside Europe. Please also include a manufacturer contact (as well as the Authorised Representative.)
g	Country	The country where the manufacturer is located.	Y	Y	Y	Y	Y	Please note: - Do not write in this field, it does not autocomplete to full entry. Please use the drop down list.
h	Street	The street of the manufacturer.	Y	Y	Y	Y	Y	Street is a mandatory field, 1.3.2 i, j and k are complement.
i	Street number	The street number of the manufacturer.	N	N	N	N	N	
j	Address complement	The address where the Manufacturer is located. E.g., building name.	N	N	N	N	N	
k	PO Box	The P.O box of the manufacturer.	N	N	N	N	N	

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l	City name	The name of the city where the manufacturer is located.	Y	Y	Y	Y	Y	
m	Postal code	The postal or zip code where the manufacturer is located.	Y	Y	Y	Y	Y	
1.3.3	**Authorized representative information**							
a	Authorised representative organisation name	The name of the Authorised representative for the device involved in this adverse incident.	Y	Y	Y	Y	Y	Mandatory properties are applicable to section 1.3.3 if manufacturer is not located within the EU /EEA/ Turkey or Northern Ireland.
b	Single registration number	SRN is the unique identifier which will be the unique identifier of actors in the future EUDAMED. When an SRN is available, an SRN field will be completed and will pre-populate in EUDAMED the Authorised representative details, including the Authorised representative's name.	Y	Y	Y	Y	Y	Please note: - The use of an SRN is not mandatory before EUDAMED becomes fully functional. If the manufacturer has not obtained an SRN yet, “Unknown” can be filled in the text field. - SRN of Manufacturer is different from the AR SRN number. - Need to obtain an SRN before submitting the MIR or uploading the XML file in future EUDAMED.
c	Contact's first name	First name of the Authorised representative contact person.	Y	Y	Y	Y	Y	
d	Contact's last name	Last name of the Authorised representative contact person.	Y	Y	Y	Y	Y	
e	Email	E-mail of the Authorised representative contact person.	Y	Y	Y	Y	Y	
f	Phone	Telephone number of the Authorised representative contact person.	Y	Y	Y	Y	Y	
g	Country	The country where the Authorised representative is located.	Y	Y	Y	Y	Y	Please note: - Do not write in this field, it does not autocomplete to full entry. Please use the drop down list.
h	Street	The street of the Authorised representative.	Y	Y	Y	Y	Y	Street is a mandatory field, 1.3.3 i, j and k are complement.
i	Street number	The street number of the Authorised representative.	N	N	N	N	N	
j	Address complement	The address where the Authorised representative is located. E.g., building name.	N	N	N	N	N	
k	PO Box	The P.O box of the Authorised representative.	N	N	N	N	N	
l	City name	The name of the city where the Authorised representative is located.	Y	Y	Y	Y	Y	
m	Postal code	The postal or zip code where the Authorised representative is located.	Y	Y	Y	Y	Y	
1.3.4	**Submitter’s details if not also manufacturer or authorised representative**							
a	Registered commercial name of company	(Third party) entities appointed to perform Vigilance reporting on behalf of the manufacturer or the Authorised Representative.	Y	Y	Y	Y	Y	Mandatory properties are applicable to section 1.3.4 if Submitter of report is 'Other'
b	Contact's first name	First name of the person to contact about the incident.	Y	Y	Y	Y	Y	
c	Contact's last name	Last name of the person to contact about the incident.	Y	Y	Y	Y	Y	
d	Email	The email address for the submitter.	Y	Y	Y	Y	Y	
e	Phone	The telephone number for the company.	Y	Y	Y	Y	Y	
f	Country	The country where the company is located.	Y	Y	Y	Y	Y	Please note: - Do not write in this field, it does not autocomplete to full entry. Please use the drop down list.
g	Street	The street of the submitter.	Y	Y	Y	Y	Y	Street is a mandatory field, 1.3.3 h, i and j are complement.
h	Street number	The street number of the submitter.	N	N	N	N	N	
i	Address complement	The address where the company is located- e.g. building name.	N	N	N	N	N	
j	PO Box	The P.O box of the submitter.	N	N	N	N	N	
k	City name	The name of the city where the company is located.	Y	Y	Y	Y	Y	
l	Postal code	The postal or zip code where the company is located.	Y	Y	Y	Y	Y	

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2.	**Medical Device Information**							
2.1	**Unique Device Identification (UDI)**							
a	(Master) UDI-DI/Eudamed ID	The Unique Device Identifier - Device Identifier (UDI-DI) UDI-DI is a unique numeric or alphanumeric code specific to a device (an unique identificator of the device itself). A unique (Primary) Identifier for a Device, Device Model, Package Structure element or Unit of Use. It is the static data portion of the UDI. e.g., a GS1 or GTIN. Master UDI-DI is the unique identifier used for grouping of certain highly individualised devices. Such highly individualised devices present specific similarities with respect to defined clinically relevant parameters (e.g. a Master UDI-DI should be assigned to contact lenses that have the same combination of contact lens design parameters, including at least base curve and diameter). Custom made devices Custom-made medical devices and performance study/investigational devices do not require a UDI. Procedure packs In cases where devices are supplied within a system or procedure pack, if an individual device is being reported on, use the UDI-DI for the device and record the system or procedure pack information in 2.6 as an associated device. If the system or procedure pack is being reported on, then use the UDI information for the system or procedure pack. Legacy devices In the event of a serious incident with a legacy device, it has to be registered in EUDAMED unless 'the same device' is already registered as a Regulation device. Exceptionally, it must also be registered in case the serious incident concerns the legacy device and not 'the same' Regulation device. An EUDAMED ID will be assigned to the device instead of the Basic UDI-DI. For the rules applicable to the registration of legacy and Regulation devices in the UDI / DEV module of EUDAMED, please refer to Questions 7, 8 & 14 of the Q&A document on gradual roll-out of EUDAMED. Old devices Old devices cannot be registered in the UDI/DEV module and, thus, will not have an UDI-DI in EUDAMED. In case an old device is the subject of a serious incident report (MIR), the manufacturer will need to provide a limited device data set to submit the relevant report in the vigilance (VGL) module (see also Question 8 of the Q&A document on gradual roll-out of Eudamed).	Y	N	N	Y	Y	Procedure Packs and Systems (MDR Article 2 (10), (11)) Legacy Devices Devices, which can continue to be placed on the market under Directive certificates by virtue of Article 120(3) of Regulation 745/2017 (MDR), and Article 110(3) of Regulation 746/2017 (IVDR) after the relevant regulation application dates. OLD devices "Old devices" are those medical devices that were placed on the market before 26 May 2021 in accordance with the AIMDD or the MDD or in accordance with the applicable rules before the Directives have entered into force and those "in-vitro diagnostic medical devices" that were placed on the market before 26 May 2022 in accordance with Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices or in accordance with the applicable rules before the Directive had entered into force. Same device: Means that Regulation device and legacy device have the same identification; such as UDI-DI., and/or catalogue/reference number and/or trade name which follows from shared characteristics. For details on the definition of "same device" and the applicable rules for registration, see Questions 8 of the Q&A gradual roll-out of EUDAMED. Issuing Entity: The Commission has designated one or several entities to operate a system for assignment of UDI's ('issuing entity'). Complete this filed by selecting from drop down the applicable designated entity (e.g., GSI, HIBCC) that your organization used to assign device information required for device registration in EUDAMED. Please note: - Issuing entity: The drop down list blank field option to be used for resetting the issuing entity. N/A (non applicable) for devices no issuing entity is involved. - This field is N/A for "old devices". - Please refer to the Delegated Regulation: Commission Delegated Regulation (EU) 2023/2197 of 10 July 2023 amending Regulation (EU) 2017/745 of the European Parliament and of the Council, as regards the assignment of Unique Device Identifiers for contact lenses (europa.eu) for further information on Master UDI-DI. - For further information on device registration and vigilance reporting please refer to the Q&A; Q&A on practical aspects related to the implementation of the gradual roll-out of Eudamed pursuant to the MDR and IVDR, as amended by Regulation (EU) 2024/1860 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices.

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b	UDI production identifier	The UDI-PI is a numeric or alphanumeric code that identifies the unit of device production. The different types of UDI-PIs include serial number, lot number, software identification and manufacturing or expiry date or both types of date. The UDI Production Identifier (PI) - default value to be 'Unknown' and for MDD/IVDD risk class devices this field is not mandatory but for MDR/IVDR risk class devices this field is mandatory. Legacy and old devices will not have an UDI PI. Please write unknown. Custom made devices and investigational devices will not have a UDI-PI. Please write unknown. The UDI Production Identifier (PI) - if unknown at time of submission please leave as 'unknown' and fill out on follow up or final if available. If two devices, with the same UDI-PI have failed in the same way you must fill out two MIR forms. Please do not add multiple UDI PIs to 1 MIR.	Y	N	N	Y	Y	Please note: - UDI PI is only required for MDR/IVDR CE certified products.
c	Basic UDI-DI/Eudamed DI	The Basic UDI-DI is the main key in the database and relevant documentation (e.g., certificates, declaration of conformity, technical documentation and summary of safety and clinical performance) to connect devices with same intended purpose, risk class and essential design and manufacturing characteristics. It is independent/separate from the packaging/labelling of the device and it does not appear on any trade item. The Basic UDI-DI shall identify the devices covered by that Basic UDI-DI in a unique manner. Basic UDI-DI is only required for EU 2017/745 or EU 2017/746 Regulation-compliant devices. Legacy devices that will be registered in EUDAMED (for specific conditions see comment section) without UDI, will need two other unique access keys (IDs) to replace the Basic UDI-DI and UDI-DI for the sake of the workability of EUDAMED (see also 2.1a). An EUDAMED DI will be assigned to the device instead of the Basic UDI-DI.	Y	N	N	Y	Y	Please note: - Issuing entity; detailed information under UDI-DI (section 2.1a). The drop down list blank field option to be used for resetting the issuing entity. N/A (non applicable) for devices no issuing entity is involved. - This field is N/A for "old devices". - Legacy devices for which no individual (sales) units are placed on the market from the date when the UDI/DEV module becomes mandatory, only need to be registered in the UDI/DEV module when the legacy device is the subject of a serious incident report (MIR) and **the same device is not** already registered as a Regulation device. - For the rules applicable to the registration of legacy and Regulation devices in the UDI / DEV module of EUDAMED, please refer to Questions 7 and 8 of the Q&A document on gradual roll-out of EUDAMED". - Same device: Means that Regulation device and legacy device have the same identification; such as UDI-DI., and/or catalogue/reference number and/or trade name which follows from shared characteristics. For the definition of "same device", see Question 8 of the Q&A document on gradual roll-out of EUDAMED.
d	Unit of use UDI-DI	An identifier assigned to an individual medical device when a UDI-DI is not labelled on the individual device at the level of its unit of use, for example in the event of several units of the same device being packaged together.	N	N	N	N	N	

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2.2	**Categorisation of device**							
a	Medical device nomenclature	Select the EMDN (or where needed the other nomenclature) code of your product (see also chapter 3, link) Field used to provide information on the medical device nomenclature used by your organization. If the nomenclature system is unavailable in drop down menu, please select other and input the system used to assign an international naming and grouping convention to your medical device. For Legacy devices select the code system that your organisation uses for legacy devices (devices with valid Directive certificate placed on the market after date of application of the Regulation).	N	N	N	N	N	Please note: - EMDN is the preferred nomenclature. EMDN primarily serves regulatory purposes to support MDR and IVDR requirements. It is intended to support all actors in their activities under the MDR/IVDR and provides key device descriptions to patients as regards their own devices and all other devices available on the market and registered in EUDAMED. - See also MDCG 2021-12; FAQ on the European Medical Device FAQ on the European Medical Device Nomenclature (EMDN)
b	Medical device nomenclature code	Enter the numeric code provided by your organization nomenclature coding system (See 2.2a) that describes the device.	N	N	N	N	N	Please note: - If a medical device nomenclature is selected (See 2.2a), providing the corresponding medical device nomenclature code that describes the device and the nomenclature text in field 2.3b becomes a mandatory requirement. - For example; When selecting EMDN please enter the EMDN Code: L010102: which is associated with the EMDN description "Scalpel blades, reusable".
2.3	**Description of device and commercial information**							
a	Medical device name (Brand/Trade/Proprietary or Common name)	The Medical device name to which this report refers. The Medical device name is defined as: *A name used to assist in the identification of the regulated medical device (source; IMDRF)* -For initial reporting, if unknown, put 'unknown' and update in a followup report when you receive the information."	Y	Y	Y	Y	Y	
b	Description of the device and its intended purpose	Description of the device and its intended use: Please briefly describe the device and its intended use of the device as outlined in the IFU. Example 1: 'Hip Implant' Example 2: 'Cardiac Marker'	Y	N	Y	Y	Y	
b	Nomenclature text	Please use primarily the EMDN nomenclature text associated with defining the code used in 2.2b. As already mentioned in right column for field 2.2.a. it is possible to use other nomenclatures than EMDN: see draft change proposal in the last column	Y	N	Y	Y	Y	Please note: - **This field only appears when selecting a nomenclature type in section 2.2a.**
c	Model	The medical device model to which this report refers. The medical device model is defined as: *the value used to represent one medical device or a family of medical devices to group many variations that have shared characteristics (source; IMDRF).*	N	N	N	N	N	
d	Catalogue/Reference number	The Catalogue/Reference number for the medical device to which this report refers. The Catalogue/Reference number is defined as: *The value given by the Regulated Entity to identify the specific medical device as it relates to its form/fit, function, and process (i.e., manufacturing processes requiring differentiation for distribution control (e.g., sterilization, component material, reprocessing, etc.) (source IMDRF).*	N	N	N	N	N	Please note: - "Regulated Entities" include: Sponsors, Applicants, Manufacturers, Labellers, Suppliers and Distributors, Maintenance/Servicing) (IMDRF).

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			Combined initial & final	Initial	Follow Up	Final (Reportable incident)	Final (Non-reportable incident)	
		The catalogue, reference number is found on the device label or accompanying packaging to identify a particular product.						
e	Serial number	The serial number for the medical device to which this report refers. The serial number is defined as: *A unique sequence of numbers or letter in a series used to identify an individual unit of a medical device (source; IMDRF).*	N	N	N	N	N	
f	Lot/batch number	The Lot/batch number for the medical device to which this report refers i.e.: *A value that represents one or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and are intended to have uniform characteristics and quality within specified limits (source; IMDRF)".*	N	N	N	N	N	
g	Software version	The software version is defined as: *The value given by the applicant to identify a specific revision of the software, including Software as a Medical Device (SaMD).*	N	N	N	N	N	Please note: - "Applicant" means any natural or legal person who is legally responsible for the medical device regulatory submission under the country or jurisdiction's legislation (IMDRF).
h	Firmware version	The firmware version is defined as: *The value given by the applicant to identify a specific revision of the firmware (including SaMD (source; IMDRF)).*	N	N	N	N	N	
i	Device manufacturing date	The date of manufacture for the medical device to which this report refers.	N	N	N	N	N	
j	Device expiry date	The expiry date for the medical device to which this report refers.	N	N	N	N	N	
k	Date when device was implanted	If available, the implant date for the medical device to which this report refers- if exact date is unknown, please add timeframe.	N	N	N	N	N	Please note that it is important to ensure the logic chronological order of the dates in 2.3.k and 2.3.l (i.e. an implant can be explanted only after it has been implanted)
l	Date when device was explanted	If available, the explant date for the medical device to which this report refers- if exact date is unknown, please add timeframe.	N	N	N	N	N	Please note that it is important to ensure the logic chronological order of the dates in 2.3.k and 2.3.l (i.e. an implant can be explanted only after it has been implanted)
m	If precise implant/explant dates are unknown, provide the duration of implantation	How long was the implant in the patient? (months/years) Please provide best estimate. If day is unknown, month and year are acceptable. If month and day are unknown, year is acceptable.	N	N	N	N	N	
n	Implant facility	The healthcare facility where the device was implanted.	N	N	N	N	N	
o	Explant facility	The healthcare facility where the device was explanted.	N	N	N	N	N	
p	Notified body (NB) ID number(s) (if applicable)	The most current identification number for the Notified Body that granted the CE mark for this device. If two Notified Bodies are involved, please enter both values in the field provided.	Y	N	N	Y	Y	Please note: - Only applicable for devices where a NB is involved in the conformity assessment procedure (i.e., devices other than MDD Class I without measuring function or sterile; IVD general; MDR class I without measuring function, sterile or reusable surgical instruments; IVDR class A without sterile conditions). - Link; *'Risk Class and NB'* properties' Guidance table for MIR section 2.3p. the mandatory properties presented in this table (see link above) are only applicable to devices for which a NB is involved in the conformity assessment procedure.
p	Notified body (NB) certificate number(s) of device (if applicable)	The certificate number from the notified body(ies) above. If two Notified Bodies, please enter both values in the fields provided (For example, a kit containing multiple components).	Y	N	N	Y	Y	Please note: - Only applicable for devices where a NB is involved in the conformity assessment procedure (see also link; *'Risk Class and NB'* properties')

	Section	Help text	Mandatory properties					Comments
			Combined initial & final	Initial	Follow Up	Final (Reportable incident)	Final (Non-reportable incident)	
q	Please indicate the date of one of the following:	What was the date of either: the first Declaration of Conformity; or the device first CE marked, or first placed on the market and/or put into service or if software, the first date available for download. For CE marked devices: the date of the first Declaration of Conformity or the date the CE Marking was affixed (these dates are usually considered to coincide but may not). For Custom-Made devices: the date the device was first placed on the market and/or put into service. Please indicate to which option the date refers.	N	N	N	N	N	Please note: this is a single choice.
2.4	**Risk class of device when placed on market**							**Select which regulation the device was conforming to <u>when it was placed</u> on the market, irrespective of when the actual incident occurred.**
a	Applicable legislation unknown		Y	Y	Y	Y	Y	One of either a, b, c or d.
b	This device has been placed on the market before the implementation of the MDD/AIMDD/IVDD	Select if the device was placed on the market before the implementation of the MDD (93/42/EEC), AIMDD (90/385/EEC) or IVDD (98/79/EC). It is possible that on the market there are devices which were placed on the market before June 1993 or active implants implanted before 1990 or an IVD before 1998.	Y	Y	Y	Y	Y	Please note: - Enter one of either a, b, c or d - If unknown please use 2.4a.
c	MDD/AIMDD/IVDD risk class	Indicate the relevant Risk Class for the medical device to which this report refers. If unknown please select risk class to the best of your knowledge and update on follow up/final. Auto populates when entering UDI-DI in Section 2.1.a.	Y	Y	Y	Y	Y	Please note: - Enter one of either a, b, c or d - If unknown please use 2.4a.
d	MDR/IVDR risk class	MDR and IVDR fields set up as according to proposal in EUDAMED The information will be attached to the UDI (Basic UDI-DI) in the UDI database; therefore, it will come automatically with the Basic UDI-DI (except for custom-made device which will not have a Basic UDI-DI). If unknown please select risk class to the best of your knowledge and update on follow up/final. Auto populates when entering UDI-DI in Section 2.1.a.	Y	Y	Y	Y	Y	Please note: - Enter one of either a, b, c or d - Type chosen can be multiple. - If unknown please use 2.4a.
e	Did this device continue to be placed on the EU market after MDR / IVDR date of application?	This field is only applicable to directive devices, solely to identify if this medical device is a legacy device.	Y	Y	Y	Y	Y	Please note: - Becomes mandatory when 2.4c is selected e.g. MDD (93/42/EEC) or IVDD (98/79/EC) compliant devices.
f	Does the device fulfil any of the following cases: -"for this device a scientific opinion has been asked in accordance with Article 52(9) MDR or Article 52(10) MDR", -"for companion diagnostic a competent authority or European Medicines Agency (EMA) was consulted in accordance with section 5.2 of Annex IX IVDR or section 3.k of Annex X IVDR."	If **<u>yes</u>** is selected, the textbox for will become mandatory. Please fill in the requested information. • <u>Competent authority name or European Medicines Agency consulted</u> by the notified body for the conformity assessment procedure described in Article 52(9) MDR or Article 52(10) MDR. For companion diagnostics (CD); the competent authority name or European Medicines Agency consulted by the notified body for the CD conformity assessment procedure described in Article 48(3) IVDR or Article 48(4) IVDR. • <u>Name(s) of the medicinal substance(s) / product(s), tissue(s), cell(s) of human origin or their derivative(s)</u> associated with the device. For companion diagnostics please provide the International Non-proprietary Name (INN) of the corresponding medicinal product.	Y	Y	Y	Y	Y	Please note: - **This field is <u>applicable to MDR (all classes) and IVDR devices (classes C or D + companion diagnostics).</u> A bullet selected in 2.4 a, b or c disactivates section 2.4 f (grey area)** - Covers both medicinal products and ancillary substances. - This field is not applicable to substances of animal origin. Some incidents may be related to: - a substance which, if used separately, would be considered to be a medicinal product. For medical devices incorporating a medicinal substance, the action of the substance is ancillary to that of the device. - substances of human origin (SOHO) i.e. derivatives of blood, tissues or cells of human origin utilised for the manufacturing of the device. For the identification of the involved tissue or cells, please add the Single European Code (SEC). - medicinal product of a companion diagnostic.

Section		Help text	Mandatory properties					Comments
			Combined initial & final	Initial	Follow Up	Final (Reportable incident)	Final (Non-reportable incident)	
								If yes selected, preliminary data or final conclusions concerning the relationship between the incident and the substances described are requested in section **4.1 b** and/or **4.2 c**, depending on the status of the report submitted.
2.5	**Market distribution of device (region/country)**							
a	**Market distribution of device (region/ country)**	Indicate which countries the medical device has been distributed to • please fill to the best of your knowledge. • Auto populates when entering UDI-DI in Section 2.1.a.	Y	N	N	Y	N	
2.6	**Use of accessories, associated devices or other devices**							
a	Relevant accessories used with the device being reported on (please list with corresponding Manufacturer if different from device being reported on)	Accessories enable the medical device to be used for its intended purpose and may or may not be from the same manufacturer as the device being reported on. Provide as much information as possible, including manufacturer names if different. This field may be used to alert the relevant NCA of the need for a separate MIR form from the other manufacturer(s) involved. 1.3.c, 2.6: If you are certain of the device that caused the incident, then this device is what should be reported on the form. - If unsure, then submit separate MIR reports on all other devices from the same manufacturer that could have played a role and fill out 1.3.1c. - List any associated accessories in 2.6a which could be from a different manufacturer if known and 2.6 b for any other devices (which could be from a different manufacturer if known).	N	N	N	N	N	Please note: - If the accessory itself is a possible cause of the incident, a separate MIR shall be submitted for that accessory. - For incident reporting an accessory has to be registered in EUDAMED. - Section 1.3c provides further details on the reporting obligations regarding the relevant accessories used with the device being reported on.
b	Relevant associated devices used with the device being reported on (please list with corresponding Manufacturer if different from device being reported on)	Associated devices are those used together/in combination and may or may not be from the same manufacturer as the device being reported on. This field may be used to alert the relevant NCA of the need for a separate MIR form from the (other) manufacturer(s) involved. - An example is the use of a CT scanner used in combination with contrast medium; contrast injectors; tubing, syringes etc. - If the manufacturer is confident that some devices present cannot be the cause of the incident, it will not submit a separate MIR for each device, but will specify them in this section. - Provide as much information as possible, including manufacturer names if different.	N	N	N	N	N	Please note: - If the NCA has doubts about the conclusion made by the manufacturer, submitting an additional MIR for other devices specified in section 2.6. might be required. - Section 1.3c provides further details on the reporting obligations regarding the relevant associated devices used with the device being reported on.

		Help text	Mandatory properties					Comments
	Section		Combined initial & final	Initial	Follow Up	Final (Reportable incident)	Final (Non-reportable incident)	
3.	**Incident information derived from initial reporter (healthcare professional/facility/patient/lay user/other)**							
3.1	**Nature of incident**							
a	Provide a comprehensive description of the incident, including (1) what went wrong with the device (if applicable) and (2) a description of the health effects (if applicable), i.e. clinical signs, symptoms, conditions as well as the overall health impact (i.e. Death; life-threatening; hospitalization – initial or prolonged; required intervention to prevent permanent damage; disability or permanent damage; congenital anomaly/Birth defects; indirect harm; no serious outcome)	Describe the incident including any relevant information that might impact the understanding or evaluation of the incident. This should cover the first observable incident or possibly a later secondary but more serious incident, or maybe both. Describe the condition/outcome of a patient after the incident, including the degree of wellness and the need for continuing care, medication, support, counselling, or education.	Y	Y	Y	Y	Y	
3.2	**Medical device problem information**							
a	IMDRF Medical device problem codes **(Annex A)**	(see also chapter 3, link) "Medical Device Problems" codes describe the problems (malfunction, deterioration of function, failure) of medical devices that have occurred in pre- or post-market contexts. The aim is to always provide the most appropriate coding level. Please enter the "most relevant" Annex A level 3 observation of the medical device problem as "Choice 1". While providing the "most relevant" code as "Choice 1" is mandatory, a manufacturer may choose to add up to 5 additional, different Annex A codes that describe the medical device problem(s). These other codes are optional. In case you cannot assign an adequate Annex A level 3 observation but a suitable Annex A level 2 code could be assigned, please use this Annex A level 2 code as "Choice 1". If it is not possible to assign an adequate Annex A level 2 code, select a suitable code of Annex A level 1 as "Choice 1". For some medical device problems, Annex A does not provide all 3 levels of terms and codes. In those cases, coding of Annex level 1 or 2 would be acceptable without justification. Since coding with IMDRF Annex A terms/codes is a mandatory requirement, “Choice 1” in Section 3.2a needs to be populated and cannot be left blank.	Y	Y	Y	Y	Y	Please note: - The PDF does not check correct IMDRF code or IMDRF code combinations. It is the responsibility of the manufacturer to provide relevant coding. Code A26 - This code can be used if there is not enough information available yet to classify the device problem on initial or follow-up MIR reporting. Code A27 - If you deem no code (on any hierarchy level) to be appropriate to describe the medical device problem, please enter code “A27 - Appropriate Term/Code Not Available” as "Choice 1" to indicate that the device problem is not adequately described by any other term. - Code A27 should not be used unless there is no other feasible code. However, in case this code is used, please briefly explain why the current terms/codes are not appropriate to describe the medical device problem. This information may be used to propose new IMDRF Adverse Event Terminology terms and codes which could be incorporated in the nomenclature as part of the ongoing maintenance process.
b	Number of patients involved	The number of patients involved. Please note that Patient could also mean user or other third person. If issue occurred without patient involvement e.g. on External Quality Assessment Samples, this field should be “0”.	N	N	N	N	N	
c	What is the current location of the device	The current location of the device involved in this event- please describe the location if none of the provided options are applicable.	Y	Y	Y	Y	Y	Please note that this is single choice.
d	Operator of device at the time of the incident	Indicate who was operating the device at the time of the event: healthcare professional, patient, Other: please describe the operator if none of the provided options are applicable.	N	N	N	N	N	Please note that this is single choice.

Section		Help text	Mandatory properties					Comments
			Combined initial & final	Initial	Follow Up	Final (Reportable incident)	Final (Non-reportable incident)	
e	Usage of device (as intended)	Indicate the usage of the device at the time the incident occurred. Please select Other if none of the provided options are applicable and describe the usage. Examples: Compassionate / humanitarian use. *For reagents/test strips:* select “initial use” as the assay itself will not be re-used (i.e., another drop of reagent or another reaction support is going to be used for the next test/sample). *For instruments/analysers*: select “Reuse of a reusable medical device” as the analyser is going to be used several years to perform testing.	N	N	N	N	N	
f	Remedial actions taken by healthcare facility, patient or user subsequent to the incident	Describe any action taken by the health practitioner, healthcare facility, patient or user to avoid a further occurrence of this problem. This may include explant of an implanted device; prescription medicine taken as a consequence of the incident; the recall of patients for further testing; or the provision of changed or improved advice on the use of the device or the quarantine of possibly affected devices / device involved in this incident.	N	N	N	N	N	
3.3	**Clinical information**							
a	IMDRF 'Health Effect' terms and codes **(Annex E, F)**	(see also chapter 3, link) Health Effect codes describe the consequence(s) of the reported incident on the patient involved. You can choose up to 6 codes to describe: 1) clinical signs, symptoms, conditions and 2) health impact. The aim is to always provide the most appropriate coding level. Please enter the most relevant lowest level observation as Choice 1. You may chose up to 5 other different codes that describe the health effect. In case you can't find a level 3 observation, but a suitable level 2 code, then please use this code as Choice 1 and explain briefly in the text box why no level 3 code was chosen. Since coding with IMDRF Annex E, F terms/codes is a mandatory requirement, “Choice 1” in Section 3.3a needs to be populated and cannot be left blank.	Y	Y	Y	Y	Y	Please note: - **The PDF does not check correct IMDRF code or IMDRF code combinations. It is the responsibility of the manufacturer to provide relevant coding.** Code E2401 or F24 - These codes can be used if there is not enough information available yet to classify the health impact on initial or follow-up MIR reporting. Code “E2402 or F28. - If you deem no code (on any hierarchy level) to be appropriate to describe 'Health Effect', please enter code “E2402 or F28 - Appropriate Term/Code Not Available” as "Choice 1" to indicate that the 'Health Effect' is not adequately described by any other term. - Code “E2402 or F28 should not be used unless there is no other feasible code. However, in case this code is used, please briefly explain why the current terms/codes are not appropriate to describe the 'Health Effect'. This information may be used to propose new IMDRF Adverse Event Terminology terms and codes which could be incorporated in the nomenclature as part of the ongoing maintenance process.
b	Age of the patient at the time of the incident, if applicable	The age of the patient is in years or months or days. Months & days should only be used for patients under the age of 1. For all others, please use years.	N	N	N	N	N	
c	Gender	The gender of the patient involved in this event (Female, Male, Other, Not specified).	N	N	N	N	N	
d	Body Weight (Kg)	The patient's weight in kilograms (Please leave blank if unknown).	N	N	N	N	N	
e	Height (cm)	The patient's height in centimetres (Please leave blank if unknown).	N	N	N	N	N	
f	List any of the patient's prior health condition or medication that may be relevant to this incident	List any health condition that may be relevant to the incident or medication taken by the patient either regularly or at the specific day/period when the incident occurred.	N	N	N	N	N	

	Section	Help text	Combined initial & final	Initial	Follow Up	Final (Reportable incident)	Final (Non-reportable incident)	Comments
3.4	**INITIAL REPORTER**							
a	Role of initial reporter	Please select the role of the person that initially reported the incident. This can be for example: healthcare professional of facility, patient, user etc.	Y	Y	Y	Y	Y	
b	Name of the health care facility where incident occurred	The name of the healthcare facility where this incident occurred. If this incident did not occur in a health care facility you don't need to fill out this field.	N	N	N	N	N	
c	Healthcare facility report number (if applicable)	The Report reference number used by the healthcare facility concerned when they reported the incident.	N	N	N	N	N	
d	Contact's first name	The name of the contact at the healthcare facility where this event occurred. If this incident did not occur in a health care facility you don't need to fill out this field.	N	N	N	N	N	
e	Contact's last name	The name of the contact at the healthcare facility where this event occurred. If this incident did not occur in a health care facility you don't need to fill out this field.	N	N	N	N	N	
f	Email	The email address for the initial reporter. If this incident did not occur in a health care facility you don't need to fill out this field.	N	N	N	N	N	
g	Phone	The telephone number for the initial reporter. If this incident did not occur in a health care facility you don't need to fill out this field.	N	N	N	N	N	
h	Country	The country where this event occurred.	Y	Y	Y	Y	Y	Please note: - <u>If other please specify;</u> the tickbox provides an option for a country not presented in the list.
i	Street	The street of the initial reporter If this incident did not occur in a health care facility you don't need to fill out this field.	N	N	N	N	N	
j	Street number	The street number of the initial reporter If this incident did not occur in a health care facility you don't need to fill out this field.	N	N	N	N	N	
k	Address complement	The address of the initial reporter If this incident did not occur in a health care facility you don't need to fill out this field.	N	N	N	N	N	
l	PO Box	The PO box of the initial reporter If this incident did not occur in a health care facility you don't need to fill out this field.	N	N	N	N	N	
m	City name	The name of the city of the initial reporter. If this incident did not occur in a health care facility you don't need to fill out this field.	N	N	N	N	N	
n	Postal code	The postal or zip code of the initial reporter. If this incident did not occur in a health care facility you don't need to fill out this field.	N	N	N	N	N	
4.	**Manufacturer analysis**							
4.1	**Manufacturer's preliminary comments**							
a	For <u>initial</u> and <u>follow-up</u> reports: preliminary results and conclusions of manufacturer's investigation	Details of any preliminary analysis you can provide.	N	Y	Y	N	N	
b	Suspicion of a relationship between the incident and the medicinal substance(s) / product(s), tissue(s), cell(s) of human origin or their derivative(s) associated with the device?	If **yes** is selected in **section 2.4f** i.e. • for this device a scientific opinion has been asked in accordance with Article 52(9) MDR or Article 52(10) MDR..	N	Y	Y	N	N	Please note: - This field is only applicable for devices referred to in section 2.4f. - If <u>tick box "Yes" is selected in field 4.1.b. but "**No" was selected under field 2.4.f.,** please reconsider your selection of tick box "No" under **2.4.f.**</u>

Section		Help text	Mandatory properties				Final (Non-reportable incident)	Comments
			Combined initial & final	Initial	Follow Up	Final (Reportable incident)		
		• for companion diagnostics(CD); the competent authority name or European Medicines Agency which delivered the scientific opinion or was consulted by the notified body for the CD conformity assessment procedure described in Article 48(3) IVDR or Article 48(4) IVDR. this field becomes **mandatory** for initial and/or follow up reports.						- Regarding the preliminary data available for initial and follow-up reports, the answer should be "No" by default unless already available data or information collected seems to or leads to a reasonable suspicion. - For Companion Diagnostics select yes if there is a suspicion or confirmation that the corresponding medicinal substance contributed to the incident.
c	Initial actions (corrective and/or preventive) implemented by the manufacturer	Details of initial corrective and/or preventive actions implemented by the manufacturer. Please add n/a if not applicable yet.	N	N	Y	N	N	
d	What further investigations do you intend in view of reaching final conclusions?	Provide details of any further investigations you plan to undertake to reach the root cause. Please add n/a if not applicable yet.	N	N	Y	N	N	
4.2	**Cause investigation and conclusion**							
a	For Final (Serious incident)- Description of the manufacturer's evaluation concerning possible root causes/causative factors and conclusion	A report of your analysis of the device involved in this serious incident. If no analysis or investigation of the device could be carried out, for example if the device was not returned, then indicate the most probable root cause analysis. Please be clear whether you are describing the root cause or most probable root cause. (Standard practice is for CA's to routinely ask for most probable root cause when it is unclear). To avoid extensive communication, give the information here. In many cases, evaluation of the actual device is not feasible. Instead the investigation may focus on "surrogate devices", i.e. devices belong to the same batch or lot as the device, to another lot/batch. Testing of model variants may also be indicated in specific cases. Please describe the devices investigated and, if applicable, tested-- Other investigative means than testing may include interviews with the user/operator of the device, control of production records etc. Your investigations and conclusions should be explained and their credibility and plausibility justified. If you refer to an existing CAPA please provide the reference or identification number of that CAPA in 4.2.g.	Y	N	N	Y	N	
b	For Final (Non-reportable incident)- Fill out rationale for why this is considered not reportable	If the incident was deemed not reportable, please indicate here why. You do not have to fill out any other additional fields. e.g. Two devices are involved and one of them was proved not to contribute to the serious incident as a result of the investigation.	N	N	N	N	Y	Please note: - Please refer to the guidance document MDCG 2023-3: Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices for further information on what is considered as a Final (Non-reportable incident).
c	Is root cause confirmed? Suspicion or confirmation of a relationship between the serious incident and the medicinal substance(s) / product(s), tissue(s), cell(s) of human origin or their derivative(s) associated with the device?	- 1st section; Please indicate if there is evidence of a causal link to the medical device problem. - 2nd section; *Suspicion or confirmation of a relationship…*; Please indicate if there is a possible causal link between the serious incident and the medicinal substance(s) /product(s), tissue (s), cell(s) of human origin or their derivative(s) associated with the device.	Y	N	N	Y	N	Please note: - The second section is only applicable for devices referred to in section 2.4f. - If tick box "Yes" is selected in field 4.2.c. but "**No" was selected under field 2.4.f.,** please reconsider your selection of tick box "No" under **2.4.f** - If tick box "Yes" is selected in field 4.1.b, Suspicion of a relationship…, a rejection or confirmation in the 2nd section of 4.2c is a mandatory requirement for final reportable and combined reports. - For Companion Diagnostics select yes if there is a suspicion or confirmation that the corresponding medicinal substance contributed to the incident.
d	Has the risks assessment been reviewed?	Indicate if the risk assessment has been reviewed after this serious incident and provide a rationale why the risk assessment is still adequate or why no review is required	Y	N	N	Y	N	Please note: • If "No" is selected in the 1st section, then the corresponding text box in the 1st section becomes mandatory.

Section		Help text	Mandatory properties				Final (Non-reportable incident)	Comments
			Combined initial & final	Initial	Follow Up	Final (Reportable incident)		
								• If "Yes" is selected in the 1st section, then "yes/ No" and the text box with the title "*Results of the assessment*" become mandatory in the 2nd section.
e	IMDRF "Cause Investigation" terms and codes **(Annex B, C, D)**	(see also chapter 3, link) "Cause Investigation" codes describe the Type of investigation (B), findings (C) and the outcome (D) of the Investigation conducted. The aim is to always provide the most appropriate coding level. Please enter the "most relevant" Annex B, C, D level 3 observation of Cause investigation as "Choice 1". While providing the "most relevant" code as "Choice 1" is mandatory, a manufacturer may choose to add up to 5 additional, different Annex codes that describe the Cause investigation. These other codes are optional. In case you cannot assign an adequate Annex B, C, D level 3 observation but a suitable Annex B, C, D level 2 code could be assigned, please use this level 2 code as "Choice 1". If it is not possible to assign an adequate Annex B, C, D level 2 code, select a suitable code of level 1 as "Choice 1". Some Annex B, C, D codes does not provide all 3 levels of terms and codes. In those cases, coding of Annex level 1 or 2 would be acceptable without justification. Since coding with IMDRF Annex B, C, D terms/codes is a mandatory requirement, "Choice 1" in Section 4.2e needs to be populated and cannot be left blank.	Y	N	N	Y	N	Please note: - **The PDF does not check correct IMDRF code or IMDRF code combinations. It is the responsibility of the manufacturer to provide relevant coding.** Cause investigation conclusion code "D17: - If you deem no code (on any hierarchy level) to be appropriate to describe the Investigation Conclusion, please enter code "D17 - Appropriate Term/Code Not Available" as "Choice 1" to indicate that the device problem is not adequately described by any other term. - Code "D17 should not be used unless there is no other feasible code. However, in case this code is used, please briefly explain why the current terms/codes are not appropriate to describe the Cause investigation conclusion. This information may be used to propose new IMDRF Adverse Event Terminology terms and codes which could be incorporated in the nomenclature as part of the ongoing maintenance process.
f	IMDRF Component codes **(Annex G)**	(see also chapter 3, link) "Component codes" codes describe medical device component characteristics. The aim is to always provide the most appropriate coding level. Please enter the "most relevant" Annex G level 3 observation of Cause investigation as "Choice 1". While providing the "most relevant" code as "Choice 1" is mandatory, a manufacturer may choose to add up to 5 additional, different Annex G codes that describe medical device components. These other codes are optional. In case you cannot assign an adequate Annex G, level 3 observation but a suitable Annex G level 2 code could be assigned, please use this level 2 code as "Choice 1". If it is not possible to assign an adequate Annex G level 2 code, select a suitable code of level 1 as "Choice 1". Some Annex G codes does not provide all 3 levels of terms and codes. In those cases, coding of Annex level 1 or 2 would be acceptable without justification. Since coding with IMDRF Annex G terms/codes is a mandatory requirement, "Choice 1" in Section 4.2f needs to be populated and cannot be left blank.	Y	N	N	Y	N	Please note: - **The PDF does not check correct IMDRF code or IMDRF code combinations. It is the responsibility of the manufacturer to provide relevant coding.** Component code G07002: - If you deem no code (on any hierarchy level) to be appropriate to describe Component codes, please enter code "G07002 - Appropriate Term/Code Not Available" as "Choice 1" to indicate that the device problem is not adequately described by any other term. - Code G07002 should not be used unless there is no other feasible code. However, in case this code is used, please briefly explain why the current terms/codes are not appropriate to describe the Component codes. This information may be used to propose new IMDRF Adverse Event Terminology terms and codes which could be incorporated in the nomenclature as part of the ongoing maintenance process.

Section		Help text	Mandatory properties					Comments
			Combined initial & final	Initial	Follow Up	Final (Reportable incident)	Final (Non-reportable incident)	
g	Description of remedial action/corrective action/preventive action/field safety corrective action (FSCA)	Describe any remedial, corrective (article 2(67)/2(70) MDR/IVDR) and/or preventative action(s) taken as a result of this event and/or your investigation. Please also include any reference number available for the remedial, corrective and/or preventive actions, including CAPA and/or FSCA (article 2(68)/2(71) MDR/IVDR). If this serious incident is covered by an existing CAPA or FSCA, please provide the reference or identification number. Note that FSCA reference number should also be given in section 1.3.1d.	Y	N	N	Y	N	Please note: - A FSCA initiated has to be reported separately by using the FSCA form. - For final and combined initial & final reports please add n/a if not applicable.
h	Time schedule for the implementation of the identified actions	Describe your time schedule for any corrective, preventative or other actions arising from this event and your investigation.	N	N	N	N	N	
i	Final comments from the manufacturer on Cause investigation and conclusion	Enter your final comments on this serious incident for cause investigation and conclusion.	N	N	N	N	N	
4.3	**Similar serious incidents (for Final serious incidents)**							
4.3.1	**Use of IMDRF terms and codes for identifying similar serious incidents**							
a	Identification of similar serious incidents using IMDRF Adverse Event Reporting terms and codes.	Are identified as similar serious incidents when: • the same device type/variant of a given manufacturer, and • having the same investigation finding (IMDRF investigation finding; Annex C) and the same medical device problem (IMDRF medical device problem; Annex A), if the investigation finding of the original serious incident is known, • or having the same medical device problem (Annex A) if the investigation finding is unknown (Annex C); notwithstanding the outcome for the patient, user or other person. When using the IMDRF Adverse Event Reporting terms and codes, it is preferable to identify and provide similar serious incident data based on the most relevant codes (this should be choice 1 in each coding section). Alternatively: Where the IMDRF 'Annex A medical device problem' and 'Annex C investigation findings' codes are not used to describe similar serious incident data, please detail how the similar serious incidents data has been calculated and the rationale for not using the IMDRF codes specified. • For example, for some implantable devices, it may be appropriate to provide similar serious incident data based on the IMDRF Health effect codes (Clinical signs, symptoms and conditions, Annex E; Health impact, Annex F). • If using these health effect codes, please use the most relevant term from either Annex E or Annex F (and not a combination of both) for identifying similar serious incidents.	Y	N	N	Y	N	For combined and final reportable MIR: • Annex A and Annex C tick box should always be mandatory for final reportable and combined reports. • The addition of Code 24 in Annex C in 2023 enabled ticking both Annexes A and C even when investigation finding is unknown.

	Section	Help text	Combined initial & final	Initial	Follow Up	Final (Reportable incident)	Final (Non-reportable incident)	Comments
4.3.2	**Use of in-house terms/codes for identifying similar serious incidents (until June 2025)**							
a	If similar serious incidents were not identified by IMDRF codes but by in-house codes, please indicate the code / combination of codes below.	Are identified as similar serious incidents when: • the same device type/variant of a given manufacturer, and • having the same root cause investigational finding, and • the same medical device problem, • the root cause investigational finding of the original serious incident is known, or having the same medical device problem if the root cause investigational finding is unknown; Notwithstanding the outcome for the patient, user or other person. When using in-house codes and terms, it is preferable to identify and provide similar serious incident data based on the most relevant code and term. Other: Where the in-house 'medical device problem' and 'root cause evaluation' terms and codes are not used to describe similar serious incident data, please detail how the similar serious incidents data has been calculated and the rationale for not using these terms/codes. For example, for some implantable devices, it may be appropriate to provide similar serious incident data based on in-house patient problem terms and codes.	N	N	N	N	N	Please note: - Please provide the used in house codes with the according terms of these codes. - Please be aware that the inhouse codes can only be used until June 2025.
4.3.3	**Number of similar serious incidents and devices on the market**							
a	Indicate on which basis similar serious incidents were identified regarding the device or device variant:	How have you defined and categorised similar serious incidents? Specify medical device identification e.g. based on model, product platform, batches, serial number range etc... that you believe is the most appropriate for categorisation of relevant similar serious incidents.	Y	N	N	Y	N	Please note that this is single choice.
b	Indicate to what criteria the number of devices on the market (also known as denominator data) is based on (tick the most appropriate)	Indicate what the numbers of devices on the market are based on. For example, number of devices sold or numbers of devices installed, number of tests performed; number of episodes of use for reusable devices (e.g. the number of episodes of use multiplied by the number of devices in service or sold). When selecting the criteria for the number of devices on the market in section 4.3.3b, manufacturers may use cumulative data for the (horizontal) time periods in section 4.3.3c. when selecting one of the following bullets and clearly explained in section 4.3.3d (mandatory): - "Active installed base" - "Number of devices implanted" - "Units distributed from the date of declaration of conformity" - "Devices placed on the market or put into service" - "Other -describe" When selecting the criteria for the number of devices on the market in 4.3.3b, competent authorities do not consider the following appropriate for the use of cumulative data for the (horizontal) time periods in section 4.3.3c - "Units distributed within each time period" - "Number of tests performed" - "Number of episodes of use"	Y	N	N	Y	N	Please note - This is single choice. - The bullet selected i.e. the criteria the number of devices on the market are based on must be clearly explained in section 4.3.3d (a mandatory requirement for combined and final reportable incident reports). - In cases of uncertainties which denominator data should be chosen, please discuss with the coordinating or NCA i.e. Manufacturers should work with the CA on the most appropriate denominator data for the device (or variant) concerned.

Section		Help text	Mandatory properties					Comments
			Combined initial & final	Initial	Follow Up	Final (Reportable incident)	Final (Non-reportable incident)	
		When these criteria are selected, the number of devices on the market should be presented within each time period.						
c	Enter the number of similar serious incidents (SI) and devices on the market for the indicated time periods	Enter, for the indicated time periods, the number of similar serious incidents (SI) and number of devices on market (i.e. denominator data should align with 4.3.3.b above). The default time period for similar serious incident data is yearly unless: 1. a different time period has been specified by the European Medical Device Vigilance Experts Group or 2. the device has not been on the European market for more than three years. In the event of (2) please clearly indicate the time periods being used to provide similar serious incident data. If selecting yearly periods, the first selection will automatically set the other time periods.	Y	N	N	Y	N	
c	Start date	The default time period as described above-If a manufacturer believes there is good reason not to use the default time period the manufacturer should approach their CA requesting agreement to use the new reporting time periods with all Competent Authorities- in the future this information/guidance can be included in the DSVGs.	Y	N	N	Y	N	Only Mandatory if using different dates from calendar years.
c	End date	The default time period as described above-If a manufacturer believes there is good reason not to use the default time period the manufacturer should approach their CA requesting agreement to use the new reporting time periods with all Competent Authorities- in the future this information/guidance can be included in the DSVGs.	Y	N	N	Y	N	Only Mandatory if using different dates from calendar years.
c	Number of similar serious incidents that occurred within each time period:	Indicate the annual cumulative number of similar serious incidents in the vertical direction. The number of similar serious incidents need to be filled out for more than one column, if the device has been on the market for more than one year. If none please add zero (type in "0"). The purpose of the data supplied by the manufacturer is for the competent authority to be able to perform risk evaluation. It needs to be possible to see the number of serious incidents per device.	Y	N	N	Y	N	Please note: - Geographical (vertical) numbers of similar incidents should always be cumulative (country of incident is part of the EEA+TR+XI and the latter is part of the world). - Reporting of the number of similar incidents should always be within each time period (horizontal) and <u>not</u> cumulative data for all time periods.
c	Number of devices on market	Indicate the annual number of devices placed on market or devices in use based on the selected option for the denominator data in section 4.3.3.b. The number of similar devices need to be filled out for more than one column, if the device has been on the market for more than one year. If none please add zero (type in "0").	Y	N	N	Y	N	Please note: - Geographical (vertical) numbers of devices on the market should always be cumulative (country is part of the EEA+TR+XI and the latter is part of the world). - Reporting of the number of devices on the market could be within each time period **or** cumulative data for all time periods based on the selected option for the denominator data selected in section 4.3.3.b and clearly explained in section 4.3.3d (mandatory requirement).

	Section	Help text	Mandatory properties					Comments
			Combined initial & final	Initial	Follow Up	Final (Reportable incident)	Final (Non-reportable incident)	
c	In country where serious incident occurred	In the country where the serious incident occurred. If none please add zero (type in "0").	Y	N	N	Y	N	
c	EEA + TR + XI	In EEA + TR + XI. If none please add zero (type in "0") This number will include the number directly above	Y	N	N	Y	N	
c	World	In the world. If none please add zero (type in "0") This number will include the number directly above.	Y	N	N	Y	N	
d	Comments on how similar serious incidents and associated number of devices on the market were determined	Based on the selected option for the denominator data in section 4.3.3.b. and the data presented in section 4.3.3c, the manufacturer should clearly explain in this section 4.3.3d how data on similar serious incidents and associated number of devices on the market were determined.	Y	N	N	Y	N	
5.	**General Comments**	Please use this section for any further comments or information that has not already been provided in the earlier sections of this report form.	N	N	N	N	N	
	Coded Summary of report (Will be auto populated from previous selections)	This section will be auto populated from previous sections for a quick overview of the coded serious incident.						Please note: - There is nothing to be filled out here by the manufacturer.
	Before signing and submitting	<u>Check the form:</u> This is an automated mandatory field check. Use this button to screen the document for mandatory fields with no data input. Output depends on type of report. <u>Save as XML or PDF:</u> Use this button to save the document in XML or PDF format within a specific location on your computer.						Please note: - Adobe Acrobat Professional is necessary for signing and XML data import/export. - Before signing the document, fields can be updated. - When a pop-up message with “check the form” appears, the submission of the MIR is blocked as long as the mandatory fields in Pop-up are not filled in. - Feedback on existing empty mandatory fields is limited to 20 notifications.
	After signing and to submit	<u>Save as XML or PDF:</u> Use this button to save the document in XML or PDF format within a specific location on your computer. <u>Submit XML or PDF by email:</u> Use this button to automatically initiate a blank email with the document in XML or PDF format attached.						Please note: - Adobe Acrobat Professional is necessary for signing and XML data import/export. - After signing the document fields are fixed. It is no longer possible to modify data. - The ‘date’ field is auto populated when signing the form. Date order (e.g. YYYY-MM-DD) is depending the geographical location (country & region settings) of the computer of the user.

Rules

Section	Question	Default status	Description
1.3.1 a	free text	disabled	Enabled if "Other, please specify" is selected
1.3.1 f	free text	disabled	Enabled if "The incident occurred within a PMCF/PMPF investigation, Yes " is selected
1.3.4 a-l	submitter	enabled	Auto populated if the submitter of the report is a Manufacturer or Authorised representative
2.2 a	free text	disabled	Enabled if "Other, please specify" is selected
2.3 b	Nomenclature text	disabled	Enabled if "2.2 a EMDN" is selected.
2.3 q	Year and Month	disabled	Enabled when any of the alternatives are selected
2.4 d	MDR Type (Multiple choice)	disabled	Enabled if an MDR class is selected.
2.4 d	IVDR Type (Multiple choice)	disabled	Enabled if an IVDR class is selected.
2.4 e	Did this device continue to be placed on the EU market after MDR / IVDR date of application?	disabled	Enabled if an MDD or IVDD risk class in section 2.4 c is selected.
2.4 f	Does “the device fulfill any of the following cases: *“for this device a scientific opinion has been asked in accordance with Article 52(9) MDR or Article 52(10) MDR", “for companion diagnostic a competent authority or EMA has been consulted in accordance with section 5.2 of Annex IX IVDR or section 3.k of Annex X IVDR."*	disabled	Enabled if "Yes" is selected
3.2 c	free text	disabled	Enabled if "Other" is selected
3.2 d	free text	disabled	Enabled if "Other, please describe" is selected
3.2 e	free text	disabled	Enabled if "Other" is selected
3.4 a	free text	disabled	Enabled if "Other, please specify" is selected
3.4 h	free text ("If other, please specify")	disabled	Enabled if "Other" is selected"
4.2 d	If 'No', rationale for no review required	disabled	Enabled if "No" ("Has the risk assessment been reviewed?") is selected
4.2 d	If the risk assessment has been reviewed, is it still adequate?	disabled	Enabled if "Yes" ("Has the risk assessment been reviewed?") is selected
4.3.1 a	Annex C (Choice 1)	disabled	Enabled if Annex A (of the same question) is selected
4.3.1 a	free text	disabled	Enabled if "Other" is selected
4.3.2 a	Annex C Code/Term	disabled	Enabled if "Code for most relevant medical device problem" (of the same question) is specified
4.3.2 a	free text	disabled	Enabled if "Other" is selected
4.3.3 b	free text	disabled	Enabled if "Other - describe" is selected

EMDN coding & IMDRF Adverse Event Terminology

	Q&A	Useful links
EMDN	**European Medical Device Nomenclature** (*used in MIR Section 2.2a)*	
Question 1	What is the European Medical Device Nomenclature (EMDN)?	
	The EMDN is a terminology and coding system for medical devices and IVD description. Per Article 26 of Regulation (EU) 2017/745 on medical devices (MDR) and Article 23 of Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), the European Medical Device Nomenclature (EMDN) aims at supporting the functioning of the European database on medical devices (EUDAMED). Among its various uses, it will be utilised by manufacturers for the registration of medical devices in EUDAMED, where it will be associated to each Unique Device Identifier – Device Identifier (UDI-DI). As the EMDN primarily serves regulatory purposes to support MDR and IVDR requirements, it also plays a key role in MDR/IVDR device documentation and technical documentation, sampling of technical documentation conducted by notified bodies, post-market surveillance, vigilance and post-market data analysis, etc. It is intended to support all actors in their activities under the MDR/IVDR and provides key device descriptions to patients as regards their own devices and all other devices available on the market and registered in EUDAMED.	European Medical Device Nomenclature (EMDN)
	Devices Nomenclature Finder	EUDAMED EMDN Device Nomenclature Finder
Question 2	How do I gain access to EMDN information?	
	The entirety of the EMDN is accessible to all stakeholders, free of charge. It can hence be utilised by a non-exhaustive list of stakeholders such as manufacturers, patients, research organisations, practitioners, hospitals, pharmacies etc. The EMDN can be accessed and downloaded in pdf and excel format and via the European Commission's website page for MDCG documents..	EMDN Q & A MDCG 2021-12
AE Terms	**The International Medical Device Regulators Forum (IMDRF) Adverse Event(AE) Terminology**	
Question 3	What is the IMDRF Adverse Event Terminology?	
	The IMDRF AE terminology is a terminology and coding system for adverse events developed by the International Medical Device Regulators Forum. It wil help regulatory agencies by enabling them to analyze safety information about medical devices with higher accuracy and reliability, and by facilitating communication about medical device adverse events between regulatory agencies using various languages. It will help regulated industry by reducing the burden of managing safety information on medical device products and reducing the burden of preparing multiple adverse event reports and other safety information to regulatory agencies. Widespread use of an improved coding system will improve signal detection by adverse event management systems enabling a faster response by both manufacturers and regulatory agencies, and reduce the burden on manufacturers in reporting common, well known adverse events.	
Question 4	Where can I find adverse event terms and codes?	
	Detailed descriptions and information about the IMDRF AE Terminology can be found on the IMDRF web browser.	IMDRF Adverse Event Terminology Web Browser
	Used in MIR section:	
	MIR Section: 3.2 (a) *Annex A: Medical device problem*	Annex A: Medical Device Problem
	MIR Section: 4.2 (e) *Annex B: Cause investigation: Type of investigation*	Annex B: Cause Investigation - Type of Investigation
	MIR Section: 4.2 (e) *Annex C: Cause investigation: Investigation findings*	Annex C: Cause Investigation - Investigation Findings
	MIR Section: 4.2 (e) *Annex D: Cause investigation: Investigation conclusion*	Annex D: Cause Investigation – Investigation Conclusion
	MIR Section: 3.3. (a) *Annex E: Clinical signs, symptoms and conditions*	Annex E: Health Effects - Clinical Signs and Symptoms or Conditions
	MIR Section: 3.3. (a) *Annex F: Health impact*	Annex F: Health Effects - Health Impact
	MIR Section: 4.2. (f) *Annex G: Components*	Annex G: Medical Device Component

Question 5	The reported incident is unique or a suitable IMDRF AE term is missing. How do I fulfil the mandatory field requirements of the MIR?
	“If exceptionally no relevant IMDRF code is available or specific enough, then provide additional information in the accompanying free text field. This is a way to propose new IMDRF terms which could be incorporated in the nomenclature during a maintenance session.

Medical Device Risk Class and Notified body properties

***Guidance table for MIR section 2.3p**. Mandatory properties presented in this table are only applicable for devices where a NB is involved in the conformity assessment procedure.*

	Combined initial & final	Initial	Follow Up	Final (Reportable incident)	Final (Non-reportable incident)
MDD/AIMDD/IVDD					
AIMD active implant	Y	N	N	Y	Y
MDD class III	Y	N	N	Y	Y
MDD class IIb	Y	N	N	Y	Y
MDD class IIa	Y	N	N	Y	Y
MDD class I	N	N	N	N	N
MDD class Is	Y (for part “sterile”)	N	N	Y (for part “sterile”)	Y (for part “sterile”)
MDD class Im	Y (for part “measuring function”)	N	N	Y (for part “measuring function”)	Y (for part “measuring function”)
MDD class Ism	Y (for part "sterile" and part “measuring function”)	N	N	Y (for part "sterile" and part “measuring function”)	Y (for part "sterile" and part “measuring function”)
IVD Annex II List A	Y	N	N	Y	Y
IVD Annex II List B	Y	N	N	Y	Y
IVD devices for self-testing	Y	N	N	Y	Y
IVD general	N	N	N	N	N
MDR/IVDR					
MDR class III	Y	N	N	Y	Y
MDR class IIb	Y	N	N	Y	Y
MDR class IIa	Y	N	N	Y	Y
MDR class I	N	N	N	N	N
MDR class I + “sterile conditions”	Y	N	N	Y	Y
MDR class I + “measuring function”	Y	N	N	Y	Y
MDR class I + “reusable surgical instruments” à yes	Y	N	N	Y	Y
IVDR class D	Y	N	N	Y	Y
IVDR class C	Y	N	N	Y	Y
IVDR class B	Y	N	N	Y	Y
IVDR class A	N	N	N	N	N
IVDR class A + "sterile conditions"	Y	N	N	Y	Y

XML Element Field Map

	Section	XML element
1.	**Administrative information**	
1.1	**Responsible competent authority in which country the incident occurred**	
a	Name of receiving national competent authority (NCA)	ncaName
b	EUDAMED Number of NCA	ncaEudamedNum
c	Reference number assigned by NCA for this incident	ncaReportNo
d	Reference number assigned by EUDAMED for this incident	refNumEudamed
1.2	**Date, type, and classification of incident report**	
a	Date of report submission	reportDate
b	Date of incident	adverseEventDateFrom adverseEventDateTo
c	Manufacturer awareness date of the incident	mfrAwarenessDate
d	Manufacturer awareness date of reportability	mfrAwarenessReportabilityDate
e	Type of Report	reportType
f	In case of initial and follow-up reports, please indicate the expected date of next report	reportNextDate
g	Classification of incident	eventClassification
1.3	**Submitter information**	
1.3.1 a	Submitter of the report	statusReporter
1.3.1 a	Submitter of the report Other text	reporterOtherText
b	Manufacturer's reference number for this incident	mfrRef
c	If this incident involves multiple devices from the same manufacturer, please list the respective reference numbers of the other MIR forms you have submitted	ncaRefMultiDev eudamedRefMultiDev mfrRefMultiDev
d	If this incident is covered under an FSCA, please provide the relevant numbers:	ncaRefFSCA eudamedRefFSCA mfrRefFSCA
e	Periodic Summary Report (PSR) ID	psrId
f	The incident occurred within a PMCF/PMPF investigation	pmcfpmpfQuestion
1.3.2	**Manufacturer information**	
a	Manufacturer Organisation name	mfrName
b	Single Registration Number (SRN)	mfrSRN
c	Contact's first name	mfrContactPersonFirstName
d	Contact's last name	mfrContactPersonSecondName
e	E-mail	mfrEmailAddress
f	Phone	mfrPhone
g	Country	mfrCountry
h	Street	mfrOrgStreet
i	Street number	mfrOrgStreetNum
j	Address complement	mfrAddress
k	P.O Box	mfrOrgPOBox
l	City name	mfrCity
m	Postcode	mfrPostcode
1.3.3	**Authorized representative information**	
a	Authorised representative Organisation name	ARName
b	Single Registration Number (SRN)	ARSRN
c	Contact's first name	ARContactPersonFirstName
d	Contact's last name	ARContactPersonSecondName
e	E-mail	AREmailAddress
f	Phone	ARPhone
g	Country	ARCountry
h	Street	ARStreet
i	Street number	ARStreetNum
j	Address complement	ARAddress
k	P.O Box	ARPOBox
l	City name	ARCity
m	Postcode	ARPostCode
1.3.4	**Submitter’s details if not also manufacturer or authorised representative**	
a	Registered commercial name of company	reporterOrgName
b	Contact's first name	reporterContactPersonFirstName
c	Contact's last name	reporterContactPersonSecondName
d	E-mail	reporterOrgEmailAddress
e	Phone	reporterOrgPhone
f	Country	reporterOrgCountry
g	Street	reporterOrgStreet
h	Street number	reporterOrgStreetNum
i	Address complement	reporterOrgAddress
j	P.O Box	reporterOrgPOBox
k	City name	reporterOrgCity

l	Postcode	reporterOrgPostcode
2.	**Medical Device Information**	
2.1	**Unique Device Identification (UDI)**	
a	(Master) UDI-DI/Eudamed ID	udiDI
a	Issuing entity	udiDI_Entity
b	UDI production identifier	udiPI
c	Basic UDI-DI/Eudamed DI	udiDIBasic
c	Issuing entity	Basic_Entity
d	Unit of use UDI-DI	udiDIUnitUse
d	Issuing entity	UnitofUse_Entity
2.2	**Categorisation of device**	
a	Medical device nomenclature	nomenclatureSystem nomenclatureSystemOther
b	Medical device nomenclature code	nomenclatureCode
2.3	**Description of device and commercial information**	
a	Medical device name (Brand/Trade/Proprietary or Common name)	brandName
b	Description of the device and its intended use	deviceDescription
b	Nomenclarture	Nomenclature
c	Model	modelNum
d	Catalogue/Reference number	catalogNum
e	Serial number(s)	serialNum
f	Lot/batch number(s)	batchNum
g	Software version	deviceSoftwareVer
h	Firmware version	deviceFirmwareVer
i	Device manufacturing date	deviceMfrDate
j	Device expiry date	deviceExpiryDate
k	Date when device was implanted	ImplantedDateFrom ImplantedDateTo
l	Date when device was explanted	ExplantedDateFrom ExplantedDateTo
m	If precise implant/explant dates are unknown, provide the duration of implantation	numYears numMonths numDays
n	Implant facility	implantFacilityName
o	Explant facility	explantFacilityName
p	Notified body (NB) ID number(s) (if applicable)	nbCertNum, nbCertNum2
p	Notified body (NB) certificate number(s) of device (if applicable)	nbIdNum, nbIdNum2
q	Please indicate the date of one of the following:	deviceMarketDateType deviceMarketDate (year, month)
2.4	**Risk class of device when placed on market**	
a	Applicable legislation	AppLegislationUnknown
b	This device has been placed on the market before the implementation of the MDD/AIMDD/IVDD	deviceClass
c	MDD/AIMDD/IVDD risk class	deviceClassMDD deviceClassIVDD

d	MDR/IVDR risk class	deviceClassMDR deviceClassIVDR deviceClassMDRType: implantable activedevice intendedtoadminister sterileconditions measuringfunction reusable software systems procedurepacks custommade non-medical deviceClassIVDRType: selftesting nearpatienttesting professionaltesting companiondiagnostics reagent software instrument sterileconditions
e	Did this device continue to be placed on the EU market after MDR / IVDR date of application	DevicePlacedMarket
f	Does the device fulfill any of the following cases: - “for this device a scientific opinion has been asked in accordance with Article 52(9) MDR or Article 52(10) MDR”, “for companion diagnostic a competent authority or European Medicines Agency (EMA) was consulted in accordance with section 5.2 of Annex IX IVDR or section 3.k of Annex X IVDR." Competent authority name or European Medicines Agency which delivered the scientific opinion or was consultedby the notified body Name(s) of the medicinal substance(s) / product(s), tissue(s), cell(s) of human origin or their derivative(s) associated with the device	DeviceFulfill CompetentAuthName RelevantName
2.5a	**Market distribution of device (region/ country)**	
a	All countries	distributionEEA
a	All EEA, Turkey and Northern Ireland	distribution_all
a	other	otherCountries
2.6	**Use of accessories, associated devices or other devices**	
a	Relevant accessories used with the device being reported on, if applicable	deviceAccessories
b	Relevant associated devices used with the device being reported on, if applicable	deviceAssociated
3.	**Incident information derived from initial reporter**	
3.1	**Nature of incident**	
a	Provide a comprehensive description of the incident, including (1) what went wrong with the device (if applicable) and (2) a description of the health effects (if applicable), i.e. clinical signs, symptoms, conditions as well as the overall health impact	eventDescription
3.2	**Medical device problem information**	
a	IMDRF Medical device problem codes (Annex A)	imdrfCodeChoice1
b	Number of patients involved	numPatientsInvolved
c	What is the current location of the device	currentDeviceLocation currentDeviceLocationOtherText
d	Operator of device at the time of the incident	deviceOperatorAtEvent deviceOperatorAtEventOther
e	Usage of device	deviceUsage deviceUsageOther
f	Remedial actions taken by healthcare facility, patient or user subsequent to the incident	patientRemedialAction
3.3	**Clinical information**	
a	IMDRF 'Health Effect' terms and codes (Annex E, F)	imdrfClinicalCodeChoice1-6 imdrfHealthCodeChoice1-6 imdrfMissingCodeHealthEffect
b	Age of the patient at the time of incident	numYearsPat numMonthsPat numDaysPat
c	Gender	Gender
d	Body Weight (Kg)	massKG
e	Height (cm)	heightCM
f	List any of the patient's prior health condition or medication that may be relevant to this incident	patientPriorMedication
3.4	**INITIAL REPORTER**	
a	Role of initial reporter	initialReporterRole initialReporterRoleOther
b	Name of the health care facility where incident occurred	healthcareFacilityName
c	Healthcare facility report number (if applicable)	healthcareFacilityRepNum
d	Contact's first name	healthcareFacilityContactPersonFirstName

e	Contact's last name	healthcareFacilityContactPersonSecondName
f	Email	healthcareFacilityEmail
g	Phone	healthcareFacilityPhone
h	Country	healthcareFacilityCountryOther
i	Street	healthcareFacilityStreet
j	Street number	healthcareFacilityStreetNum
k	Address complement	healthcareFacilityAddress
l	P.O Box	healthcareFacilityPOBox
m	City name	healthcareFacilityCity
n	Postcode	healthcareFacilityPostcode

4. Manufacturer analysis

4.1 Manufacturer's preliminary comments

a	For initial and follow-up reports: preliminary results and conclusions of manufacturer's investigation	manufacturersPrelimAnalysis
b	Suspicion of a relationship between the incident and the medicinal substance(s) / product(s), tissue(s), cell(s) of human origin or their derivative(s) associated with the device?	suspicionRelationShip
c	Initial actions (corrective and/or preventive) implemented by the manufacturer	manufacturersInitialCorrecAction
d	What further investigations do you intend in view of reaching final conclusions	furtherInvestigations

4.2 Cause investigation and conclusion

a	For Final (Reportable incident)- Description of the manufacturer's evaluation concerning possible root causes/causative factors and conclusion	rootCauses
b	For Final (Non-reportable incident)- Fill out rationale for why this is considered not reportable	manufacturersWhyNotReportable
c	Is root cause confirmed	rootCauseConfirmed
	Suspicion or confirmation of a relationship between the serious incident and the medicinal substance(s) /product(s), tissue (s), cell(s) of human origin or their derivative(s) associated with the device?	relationShipIncidentSubstance
d	Has the risks assessment been reviewed?	riskAssReviewed rationaleNoReview riskAssAdequate riskAssResults
e	IMDRF 'Cause Investigation' terms and codes (Annex B, C, D)	imdrfTypeInvestigationCodeChoice1-8 imdrfInvestigationFindingsCodeChoice1-6 imdrfInvestigationConclusionCodeChoice1-6 imdrfMissingCodeCauseInvestigation
f	IMDRF Component codes (Annex G)	imdrfComponentCodeChoice1-6 imdrfMissingComponentCodes
g	Description of remedial action/corrective action/preventive action/Field Safety Corrective Action	correctiveAction
h	Time schedule for the implementation of the identified actions	correctiveActionSchedule
i	Final comments from the manufacturer on cause investigation and conclusion	manufacturersFinalComments

4.3 Similar (serious) incidents (for Final Reportable incident)

4.3.1 Use of IMDRF terms and codes for identifying similar (serious) incidents

a	Identification of similar(serious) incidents using IMDRF Adverse Event Reporting terms and codes. T	similarIncImdrfCodesAnnexA similarIncImdrfCodesAnnexC similarIncOtherReportingCodes similarIncOtherReportingCodesText

4.3.2 Use of in-house terms/codes for identifying similar (serious) incidents

a	If similar incident were not identified by IMDRF codes but by in-house codes, please indicate the code/combination of codes below.	similarIncMdCodesChoice1Code similarIncMdCodesChoice1Term similarIncRootCouseCodesChoice1Code similarIncRootCouseCodesChoice1Term similarIncOtherInHouseCodes similarIncOtherInHouseCodesText

4.3.3 Number of similar (serious) incidents and devices on the market

a	Indicate on which basis similar (serious) incidents were identified regarding the device or device variant:	similarVariant similarVariantDetails
b	Indicate to what criteria the number of devices on the market (also known as denominator data) is based on (tick the most appropriate)	numberBasedOn numberBasedOnOther
c	Start date	startDateN - startDateN-3
c	End date	endDateN - endDateN-3
c	In country where incident occurred (Number of similar incidents)	countrySimIncN - countrySimIncN-3
c	In country where incident occurred (Number of devices on market)	countrySimDevN - countrySimDevN-3
c	EEA + candidate countries + CH + TR (Number of similar incidents)	eeaChTrSimIncN - eeaChTrSimIncN-3
c	EEA + candidate countries + CH + TR (Number of devices on market)	eeaChTrSimDevN - eeaChTrSimDevN-3
c	World (Number of similar incidents)	worldSimIncN - worldSimIncN-3
c	World (Number of devices on market)	worldSimDevN - worldSimDevN-3
d	Comments on how similar (serious) incidents and associated number of devices on the market were determined	howWereDetermined

5. General Comments

	General Comments	AdditionalComments

Coded Summary of report (Will be auto populated from previous selections)

Submission part

Date sCreateTimeStamp