

Manufacturer Incident Report (MIR) for Serious Incidents (MDR/IVDR) and Incidents (AIMDD/MDD/IVDD)

Reporting Template Version 7.2
European Union Medical Devices Vigilance System

Section 1: Administrative information

1.1 Corresponding competent authority

a	Name of receiving national competent authority (NCA) <input type="text"/>
b	EUDAMED number of NCA <input type="text"/>
c	Reference number assigned by NCA for this incident <input type="text"/>
d	Reference number assigned by EUDAMED for this incident <input type="text"/>

1.2 Date, type, and classification of incident report

a	Date of submission <input type="text"/> (e.g. 2012-10-23)	b	Date of incident (e.g. 2012-10-23) <input type="text"/> to <input type="text"/>	c	Manufacturer awareness date <input type="text"/> (e.g. 2012-10-23)
d	Type of report <input type="radio"/> Initial <input type="radio"/> Follow up <input type="radio"/> Combined initial and final <input type="radio"/> Final (Reportable incident) <input type="radio"/> Final (Non-reportable incident)				
e	In case of initial and follow-up reports, please indicate the expected date of the next report <input type="text"/> (e.g. 2012-10-23)				
f	Classification of incident <input type="radio"/> Serious public health threat <input type="radio"/> Death <input type="radio"/> Unanticipated serious deterioration in state of health <input type="radio"/> All other reportable incidents				

1.3 Submitter information

1.3.1 Submitter of the report

a	<input type="radio"/> Manufacturer <input type="radio"/> Authorised representative <input type="radio"/> Other, please specify <input type="text"/>
b	Manufacturer's reference number for this incident <input type="text"/>

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 - NCA's local reference number <input type="text"/> - EUDAMED's reference number <input type="text"/> - Manufacturer's reference number <input type="text"/>		
d	If this incident is covered under an FSCA, please provide the relevant numbers: - NCA's local FSCA reference number <input type="text"/> - EUDAMED's FSCA reference number <input type="text"/> - Manufacturer's FSCA reference number <input type="text"/>		
e	Periodic Summary Report (PSR) ID <input type="text"/>		
f	If the incident occurred within a PMCF/PMPF investigation; please provide the Eudamed ID of that PMCF/PMPF investigation <input type="text"/>		
1.3.2 Manufacturer information			
a	Manufacturer organisation name <input type="text"/>		
b	Single registration number <input type="text"/>		
c	Contact's first name <input type="text"/>	d	Contact's last name <input type="text"/>
e	Email <input type="text"/>	f	Phone <input type="text"/>
g	Country <input type="text"/>		
h	Street <input type="text"/>	i	Street number <input type="text"/>
j	Address complement <input type="text"/>	k	PO Box <input type="text"/>
l	City name <input type="text"/>	m	Postal code <input type="text"/>
1.3.3 Authorised representative information			
a	Authorised representative organisation name <input type="text"/>		
b	Single Registration Number <input type="text"/>		
c	Contact's first name <input type="text"/>	d	Contact's last name <input type="text"/>
e	Email <input type="text"/>	f	Phone <input type="text"/>
g	Country <input type="text"/>		

h	Street <input type="text"/>	i	Street number <input type="text"/>
j	Address complement <input type="text"/>	k	PO Box <input type="text"/>
l	City name <input type="text"/>	m	Postal code <input type="text"/>
1.3.4 Submitter's details if not also manufacturer or authorised representative			
a	Registered commercial name of company <input type="text"/>		
b	Contact's first name <input type="text"/>	c	Contact's last name <input type="text"/>
d	Email <input type="text"/>	e	Phone <input type="text"/>
f	Country <input type="text"/>		
g	Street <input type="text"/>	h	Street number <input type="text"/>
i	Address complement <input type="text"/>	j	PO Box <input type="text"/>
k	City name <input type="text"/>	l	Postal code <input type="text"/>

Section 2: Medical device information

2.1	Unique Device Identification (UDI)	
a	UDI device identifier/Eudamed ID <input type="text" value="Unknown"/>	b UDI production identifier <input type="text" value="Unknown"/>
c	Basic UDI-DI/Eudamed-DI <input type="text" value="Unknown"/>	d Unit of use UDI-DI <input type="text"/>
2.2	Categorisation of device	
a	Medical device terminology <input type="radio"/> EMDN <input type="radio"/> GMDN <input type="radio"/> UMDNS(ECRI) <input type="radio"/> GIVD/EDMS <input type="radio"/> Other, please specify <input type="text"/>	
b	Medical device nomenclature code <input type="text"/>	
2.3	Description of device and commercial information	
a	Medical device name (brand/trade /proprietary or common name) <input type="text"/>	
b	Nomenclature text/Description of the device and its intended use <input type="text"/>	
c	Model <input type="text"/>	d Catalogue/reference number <input type="text"/>
e	Serial number <input type="text"/>	f Lot/batch number <input type="text"/>
g	Software version <input type="text"/>	h Firmware version <input type="text"/>
i	Device manufacturing date (e.g. 2012-10-23) <input type="text"/>	j Device expiry date (e.g. 2012-10-23) <input type="text"/>
k	Date when device was implanted (e.g. 2012-10-23) <input type="text"/> to <input type="text"/>	l Date when device was explanted (e.g. 2012-10-23) <input type="text"/> to <input type="text"/>
m	If precise implant/explant dates are unknown, provide the duration of implantation Number of years <input type="text"/> Number of months <input type="text"/> Number of days <input type="text"/>	
n	Implant facility <input type="text"/>	o Explant facility <input type="text"/>
p	Notified body (NB) ID number(s) (if applicable) 1 <input type="text"/> 2 <input type="text"/>	Notified body (NB) certificate number(s) of device (if applicable) <input type="text"/> <input type="text"/>
q	Please indicate the date of <u>one</u> of the following: <input type="radio"/> First declaration of conformity <input type="radio"/> The device first CE marked <input type="radio"/> First placed on the market <input type="radio"/> First put into service <input type="radio"/> If software, date first made available Year <input type="text"/> Month <input type="text"/>	

2.4	Risk class of device when placed on market			
a	<input type="radio"/> This device has been placed on the market before the implementation of the MDD/AIMDD/IVDD			
b	<u>MDD/AIMDD</u> <input type="radio"/> active implant <input type="radio"/> class III <input type="radio"/> class IIb <input type="radio"/> class IIa <input type="radio"/> class I <input type="radio"/> class Is <input type="radio"/> class Im <input type="radio"/> class Ism <input type="radio"/> custom-made		<u>IVDD</u> <input type="radio"/> IVD Annex II List A <input type="radio"/> IVD Annex II List B <input type="radio"/> IVD devices for self-testing <input type="radio"/> IVD general	
c	<u>MDR</u> <input type="radio"/> class III <input type="radio"/> class IIb <input type="radio"/> class IIa <input type="radio"/> class I	<u>Type (Multiple choice)</u> <input type="checkbox"/> implantable <input type="checkbox"/> active device <input type="checkbox"/> intended to administer and/or remove a medicinal product <input type="checkbox"/> sterile conditions <input type="checkbox"/> measuring function <input type="checkbox"/> reusable surgical instruments <input type="checkbox"/> software <input type="checkbox"/> systems <input type="checkbox"/> procedure packs <input type="checkbox"/> custom-made <input type="checkbox"/> non-medical purpose	<u>IVDR</u> <input type="radio"/> class D <input type="radio"/> class C <input type="radio"/> class B <input type="radio"/> class A	<u>Type (Multiple choice)</u> <input type="checkbox"/> self-testing <input type="checkbox"/> near-patient testing <input type="checkbox"/> professional testing <input type="checkbox"/> companion diagnostic <input type="checkbox"/> reagent <input type="checkbox"/> software <input type="checkbox"/> instrument <input type="checkbox"/> sterile conditions
2.5	Market distribution of device (region/country) (according to the best knowledge of the manufacturer)			
a	<input type="checkbox"/> All EEA, Switzerland and Turkey <div> <input type="checkbox"/> AT <input type="checkbox"/> BE <input type="checkbox"/> BG <input type="checkbox"/> CH <input type="checkbox"/> CY <input type="checkbox"/> CZ <input type="checkbox"/> DE <input type="checkbox"/> DK <input type="checkbox"/> EE <input type="checkbox"/> ES <input type="checkbox"/> FI <input type="checkbox"/> FR <input type="checkbox"/> GB <input type="checkbox"/> GR <input type="checkbox"/> HR <input type="checkbox"/> HU <input type="checkbox"/> IE <input type="checkbox"/> IS <input type="checkbox"/> IT <input type="checkbox"/> LI <input type="checkbox"/> LT <input type="checkbox"/> LU <input type="checkbox"/> LV <input type="checkbox"/> MT <input type="checkbox"/> NL <input type="checkbox"/> NO <input type="checkbox"/> PL <input type="checkbox"/> PT <input type="checkbox"/> RO <input type="checkbox"/> SE <input type="checkbox"/> SI <input type="checkbox"/> SK <input type="checkbox"/> TR </div> Others: <input type="text"/>			
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) <input type="text"/>			
b	Relevant associated devices used with the device being reported on (please list with corresponding Manufacturer if different from device being reported on) <input type="text"/>			

Section 3: Incident information derived from 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)

3.2 Medical device problem information

- a** IMDRF Medical device problem codes (Annex A)
Coding with IMDRF terms is a mandatory requirement.

	Choice 1 (most relevant)	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Medical device problem codes'	Code <div></div>	Code <div></div>	Code <div></div>	Code <div></div>	Code <div></div>	Code <div></div>

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

- b** Number of patients involved

- c** What is the current location of the device?

- ☐ Healthcare facility/carer ☐ Distributor
☐ Patient/user ☐ Discarded
☐ In transit to manufacturer ☐ Remains implanted
☐ Manufacturer ☐ Unknown ☐ Other:

- d** Operator of device at the time of the incident

- ☐ Healthcare professional ☐ Patient/lay user ☐ Other, please describe

- e** Usage of device (as intended)

- ☐ Initial use ☐ Reuse of a single use medical device
☐ Reuse of a reusable medical device ☐ Re-serviced/refurbished/fully refurbished
☐ Problem noted prior use ☐ Other:

- f** Remedial actions taken by healthcare facility, patient or user subsequent to the incident

3.3	Patient information						
a	IMDRF 'Health Effect' terms and codes (Annex E, F) Coding with IMDRF terms is a mandatory requirement.						
		Choice 1 (most relevant)	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
	IMDRF 'Clinical signs, symptoms, and conditions codes' (Annex E)	Code <input type="text"/>	Code <input type="text"/>	Code <input type="text"/>	Code <input type="text"/>	Code <input type="text"/>	Code <input type="text"/>
	IMDRF 'Health impact' codes (Annex F)	Code <input type="text"/>	Code <input type="text"/>	Code <input type="text"/>	Code <input type="text"/>	Code <input type="text"/>	Code <input type="text"/>
	If you think the incident is unique and a suitable IMDRF term is missing, briefly explain: <input type="text"/>						
b	Age of patient at the time of the incident years <input type="text"/> months <input type="text"/> days <input type="text"/>						
c	Gender <input type="radio"/> Female <input type="radio"/> Male <input type="radio"/> Unknown <input type="radio"/> Not applicable						
d	Body weight (kg) <input type="text"/>						
e	List any of the patient's prior health condition or medication that may be relevant to this incident <input type="text"/>						
3.4	Initial reporter (can be healthcare professional of facility, patient, lay user)						
a	Role of initial reporter <input type="radio"/> Healthcare professional <input type="radio"/> Patient <input type="radio"/> Lay user <input type="radio"/> Other, please specify <input type="text"/>						
b	Name of healthcare facility where incident occurred <input type="text"/>						
c	Healthcare facility report number (if applicable) <input type="text"/>						
d	Contact's first name <input type="text"/>		e	Contact's last name <input type="text"/>			
f	Email <input type="text"/>		g	Phone <input type="text"/>			
h	Country <input type="text"/>						
i	Street <input type="text"/>		j	Street number <input type="text"/>			
k	Address complement <input type="text"/>		l	PO Box <input type="text"/>			
m	City name <input type="text"/>		n	Postal code <input type="text"/>			

Section 4: Manufacturer analysis

4.1 Manufacturer's preliminary comments

a

For **initial** and **follow-up** reports: preliminary results and conclusions of manufacturer's investigation

b

Initial actions (corrective and/or preventive) implemented by the manufacturer

c

What further investigations do you intend in view of reaching final conclusions?

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

b

For Final (Non-reportable incident): Fill out rationale for why this is considered not reportable

c

Is root cause confirmed?

☐ Yes ☐ No

d

Has the risk assessment been reviewed?

☐ Yes

☐ No If 'No', rationale for no review required:

If the risk assessment has been reviewed, is it still adequate?

☐ Yes

☐ No

Results of the assessment:

e	IMDRF 'Cause Investigation' terms and codes (Annex B, C, D)								
	Coding with IMDRF terms is a mandatory requirement.	Choice 1 (most relevant)	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6	Choice 7	Choice 8
	IMDRF Cause investigation: Type of investigation (Annex B)	Code <input type="text"/>	Code <input type="text"/>	Code <input type="text"/>	Code <input type="text"/>	Code <input type="text"/>	Code <input type="text"/>	Code <input type="text"/>	Code <input type="text"/>
	IMDRF Cause investigation: Investigation findings (Annex C)	Code <input type="text"/>	Code <input type="text"/>	Code <input type="text"/>	Code <input type="text"/>	Code <input type="text"/>	Code <input type="text"/>		
	IMDRF Cause investigation: Investigation conclusion (Annex D)	Code <input type="text"/>	Code <input type="text"/>	Code <input type="text"/>	Code <input type="text"/>	Code <input type="text"/>	Code <input type="text"/>		
If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:									
<input type="text"/>									
f	IMDRF Component codes (Annex G)								
	Coding with IMDRF terms is a mandatory requirement.								
		Choice 1 (most relevant)	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6		
IMDRF 'Component' codes (Annex G)		Code <input type="text"/>	Code <input type="text"/>	Code <input type="text"/>	Code <input type="text"/>	Code <input type="text"/>	Code <input type="text"/>	Code <input type="text"/>	
If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:									
<input type="text"/>									
g	Description of remedial action/corrective action/preventive action/field safety corrective action (FSCA)								
<input type="text"/>									
(For a FSCA, fill in the FSCA form)									
h	Time schedule for the implementation of the identified actions								
<input type="text"/>									
i	Final comments from the manufacturer on cause investigation and conclusion								
<input type="text"/>									

4.3	Similar incidents (for Final (Reportable incident))						
4.3.1	Use of IMDRF terms and codes for identifying similar incidents						
a	<p>Identification of similar incidents using IMDRF Adverse Event Reporting terms and codes Tick-mark which code or combination of codes were used for identifying similar incidents.</p> <table border="1"> <thead> <tr> <th></th><th>Choice 1</th></tr> </thead> <tbody> <tr> <td>IMDRF code relating to most relevant 'Medical device problem' (Annex A)</td><td><input type="checkbox"/></td></tr> <tr> <td>IMDRF code relating to most relevant 'Investigation finding' (Annex C, 'Cause investigation')</td><td><input type="checkbox"/></td></tr> </tbody> </table> <p><input type="checkbox"/> Other – enter description of what similar incidents are based on and the rationale why the above IMDRF codes were not used</p> <div></div>		Choice 1	IMDRF code relating to most relevant 'Medical device problem' (Annex A)	<input type="checkbox"/>	IMDRF code relating to most relevant 'Investigation finding' (Annex C, 'Cause investigation')	<input type="checkbox"/>
	Choice 1						
IMDRF code relating to most relevant 'Medical device problem' (Annex A)	<input type="checkbox"/>						
IMDRF code relating to most relevant 'Investigation finding' (Annex C, 'Cause investigation')	<input type="checkbox"/>						
4.3.2	Use of in-house terms/codes for identifying similar incidents (only for transition period)						
a	<p>If similar incident were not identified by IMDRF codes but by in-house codes, please provide the codes and terms below.</p> <table border="1"> <thead> <tr> <th></th><th>Choice 1</th></tr> </thead> <tbody> <tr> <td>Code/term for most relevant medical device problem</td><td> <div>Code <input type="text"/></div> <div>Term <input type="text"/></div> </td></tr> <tr> <td>Code/term for most relevant root cause evaluation</td><td> <div>Code <input type="text"/></div> <div>Term <input type="text"/></div> </td></tr> </tbody> </table> <p><input type="checkbox"/> Other – enter description of what similar incidents are based on and the rationale why the above codes were not used</p> <div></div>		Choice 1	Code/term for most relevant medical device problem	<div>Code <input type="text"/></div> <div>Term <input type="text"/></div>	Code/term for most relevant root cause evaluation	<div>Code <input type="text"/></div> <div>Term <input type="text"/></div>
	Choice 1						
Code/term for most relevant medical device problem	<div>Code <input type="text"/></div> <div>Term <input type="text"/></div>						
Code/term for most relevant root cause evaluation	<div>Code <input type="text"/></div> <div>Term <input type="text"/></div>						
4.3.3	Number of similar incidents and devices on the market						
a	<p>Indicate on which basis similar incidents were identified regarding the device or device variant: <input type="radio"/> Model <input type="radio"/> Software <input type="radio"/> Lot/Batch <input type="radio"/> Product platform <input type="radio"/> Other variant</p> <p>Details of the selection made above</p> <div></div>						
b	<p>Indicate to what criteria the number of devices on the market (also known as denominator data) is based on (tick the most appropriate):</p> <p> <input type="radio"/> Devices placed on the market or put into service <input type="radio"/> Units distributed within each time period <input type="radio"/> Number of tests performed <input type="radio"/> Number of episodes of use (for reusable devices) <input type="radio"/> Active installed base <input type="radio"/> Units distributed from the date of declaration of conformity/CE mark approval to the end date of each time period <input type="radio"/> Number of devices implanted <input type="radio"/> Other -describe </p> <div></div>						

c

Enter the number of similar incidents and devices on the market for the indicated time periods

You must use yearly time periods unless:

A: a different time period has been specified by the European vigilance Working Group

B: the device has not been on the European market for more than three years

	Time period (N) Year to date = incident year (e.g. 2012-10-23)		Time period (N-1) calendar year one year before incident (e.g. 2012-10-23)		Time period (N-2) calendar year two years before incident (e.g. 2012-10-23)		Time period (N-3) calendar year three years before incident (e.g. 2012-10-23)	
Start date	<input type="text"/>		<input type="text"/>		<input type="text"/>		<input type="text"/>	
End date	<input type="text"/>		<input type="text"/>		<input type="text"/>		<input type="text"/>	
	Number of similar incidents	Number of devices on market	Number of similar incidents	Number of devices on market	Number of similar incidents	Number of devices on market	Number of similar incidents	Number of devices on market
Country of incident	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
EEA + CH + TR	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
World	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

d

Comments on how similar incidents and associated number of devices on the market were determined

Section 5: General comments

Coded summary of report (will be auto populated from previous selections)									
Medical device name <input type="text"/>									
Basic UDI-DI <input type="text" value="Unknown"/>									
UDI device identifier <input type="text" value="Unknown"/>				UDI production identifier <input type="text" value="Unknown"/>					
IMDRF adverse event reporting terms and codes IMDRF=International Medical Device Regulators Forum. Coding with IMDRF terms is a mandatory requirement.									
IMDRF clinical signs, symptoms, conditions codes				<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
IMDRF health impact codes				<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
IMDRF Medical device problem codes				<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
IMDRF Component codes				<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
IMDRF Cause investigation: Type of investigation				<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
IMDRF Cause investigation: Investigation findings.				<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
IMDRF Cause investigation: Investigation conclusion.				<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Submission of this report does not represent a conclusion by the manufacturer and / or authorised representative or the national competent authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

I affirm that the information given above is correct to the best of my knowledge.

Before signing and submitting

<input type="button" value="Check the form"/>	<input type="button" value="Save as PDF"/>
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Date <input type="text"/>

Signature/Digital Signature <input type="text"/>

<input type="button" value="Send as XML file"/>	<input type="button" value="Submit XML by Email"/>
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<input type="button" value="Send as PDF file"/>	<input type="button" value="Submit PDF by Email"/>
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