General : If the value of a field is unknown and the fie
Only fields 2.1 a,b,c default to 'unknown' as this is a requirement for electroni
The form should be used to report Incidents and Serious Incidents u

	Section	Help text	Combined initial & final
	1. Administrative information		
	1,1 Corresponding competent authority		
a	Name of receiving national competent authority (NCA)	NCA to which the report is being sent	Y
b	EUDAMED Number of NCA	Unique Eudamed number of NCA (could be auto filled/selected once Eudamed available)	N
c	Reference number assigned by NCA	The reference number of the NCA for this incident (if known- i.e. follow up and finals). If not known please add 'not known'	N
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
	1,2 Date, type, and classification of incident report		
a	Date of submission	Date when you submit the report	Y

b	Date of incident	Date when incident happened - if incident date is unknown please add the dates between 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. 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 time-span you need to adjust the second field accordingly.	Y
c	Manufacturer awareness date	Date when company employee was made aware of the incident	Y

d	Type of Report	Initial Report - Choose this for your first report on a particular incident. 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 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 recognised that a further 'Final' report may be necessary in circumstances where additional information only becomes available at a later stage. Note this option is only available once you have submitted an initial report. Applicable for both vigilance reports submitted in compliance with MDD/IVDD (30 days) and for MDR/IVDR (15 days) Final (Non-reportable incident)- This is to be used if the event reported in the initial vigilance report is found after analysis not to fulfil the reporting criteria. By selecting this the only mandatory field is the 4.2a and no other fields in Section 4	Y
e	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

f	Classification of incident	Please classify the incident according with the following definitions: Serious public health threat: An event 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: The event led to the death of a patient, user or other person. Unanticipated serious deterioration in state of health: An unanticipated serious deterioration in state of health is one where the event was not considered in a risk analysis, and where it led to a serious deterioration in the state of health of a patient, user or other person. All other reportable incidents: These are events which did not involve a death and which were not unanticipated but which led, or might have led, to a serious deterioration in the state of health of a patient, user or other person.	Y

1,3 Submitter information

1.3.1 a	Submitter of report	Who is submitting the report	Y
b	Manufacturer's reference number for this incident	The reference number assigned by the manufacturer	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 devices are listed) Please use a semi colon to separate multiple values	N

d	If this incident is covered under an FSCA, please provide the relevant numbers:	NCA's local FSCA reference - The NCA reference number assigned to the FSCA that this incident covers EUDAMED's FSCA reference number Manufacturer's FSCA reference number - 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
e	Periodic Summary Report (PSR) ID	Please quote the unique PSR-ID for the incident if it is reportable under PSR. If under PSR then you must fill this out (The PSR task force is working up a new methodology for PSR submission . This field is here as a placeholder to facilitate this new method of submission.) Please use a semi colon to separate multiple values	N
f	If the incident occurred within a PMCF/ PMPF investigation; please provide the Eudamed ID of that PMCF/PMPF investigation	If the incident occurred during a PMCF/PMPF investigation then you must fill this out. The word 'studies' is generally used for PMCF/PMPF however the MDR refers to this as 'investigation'	N
1.3.2	**Manufacturer information**		
a	Manufacturer Organisation name	The name of the Manufacturer for the device involved in this adverse incident	Y
b	Single Registration Number (SRN)	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 the manufacturer details, including the Manufacturer's name.	Y

	Contact's first name	First name of the manufacturer contact person	Y
c			
	Contact's last name	Last name of the manufacturer contact person	Y
d			

	E-mail	E-mail of the manufacturer contact person .	Y
e			
	Phone	Telephone number of the manufacturer contact person	Y
f			
g	Country	The country where the manufacturer is located. (Note for development- drop down with ISO code and it should be worldwide)	Y
h	Street	The street of the manufacturer	Y
i	Street number	The street number of the manufacturer	N
j	Address complement	The address where the Manufacturer is located. E.g. building name	N
k	P.O Box	The P.O box of the manufacturer	N
l	City name	The name of the city where the manufacturer is located.	Y
m	Postcode	The postal or zip code where the manufacturer is located	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
b	Single Registration Number (SRN)	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 the Authorised representative details, including the Authorised representative's name.	Y
c	Contact's first name	First name of the Authorised representative contact person	Y
d	Contact's last name	Last name of the Authorised representative contact person	Y
e	E-mail	E-mail of the Authorised representative contact person .	Y
f	Phone	Telephone number of the Authorised representative contact person	Y
g	Country	The country where the Authorised representative is located.	Y
h	Street	The street of the Authorised representative	Y
i	Street number	The street number of the manufacturer Autorised representative	N
j	Address complement	The address where the Authorised representative is located. E.g. building name	N
k	P.O Box	The P.O box of the Authorised representative	N
l	City name	The name of the city where the Authorised representative is located.	Y
m	Postcode	The postal or zip code where the Authorised representative is located	Y
1.3.4	**Submitters details if not manufacturer or authorized representative**		
a	Registered commercial name of company	The name of the company for this adverse incident	Y
b	Contact's first name	First name of the person to contact about the incident	Y
c	Contact's last name	Last name of the person to contact about the incident	Y

d	E-mail	The email address for the submitter	Y
e	Phone	The telephone number for the company	Y
f	Country	The country where the company is located. (Note for development- drop down with ISO code and it should be worldwide)	Y
g	Street	The street of the submitter	Y
h	Street number	The number of the manufacturer on the street	Y
i	Address complement	The address where the company is located- e.g. building name	N
j	P.O Box	The P.O box of the submitter	N
k	City name	The name of the city where the company is located.	N
l	Postcode	The postal or zip code where the company is located	Y

2. Medical Device Information

2,1 Unique Device Identification (UDI)

a	UDI device identifier	The UDI Device Identifier (DI). 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.	Y

	UDI production identifier	The UDI Production Identifier (PI) - if unknown at time of submission please leave as 'unknown' and fill out on follow up or final.	Y
b			
	Basic UDI-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. Any Basic UDI-DI shall identify the devices (group) covered by that Basic UDI-DI in a unique manner.	Y
c			
	Unit of use UDI-DI	Identifier assigned to an individual medial 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
d			
2,2	**Categorisation of device**		
a	Medical Device terminology used	Select the code system that your organisation uses	N
b	Medical device nomenclature code	Code from the terminology above	N

2,3	**Description of device and commercial information**	(IMDRF definitions from the published 'Common Data Elements for Medical Device Identification' document are used here- indicated with IMDRF after the definition. (http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-rps-common-data-elements.pdf)	
a	Medical device name (Brand/Trade/Proprietary or Common name)	A name used to assist in the identification of the regulated medical device (IMDRF) - If unknown , put 'unknown' and update when you receive the information.	Y
b	Nomenclature text/Description of the device and its intended use	Nomenclature text: can be the same as the text defining the code in 2.2b Or Description of the device and its intended use: Please describe the intended use of the device as foreseen in the IFU.	Y
c	Model	The value used to represent one medical device or a family of medical devices to group many variations that have shared characteristics (IMDRF).	N
d	Catalogue/Reference number	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.) (IMDRF)	N
e	Serial number(s)	The serial number(s) for the medical device to which this report refers	N
f	Lot/batch number(s)	The Lot/batch number(s) number for the medical device to which this report refers	N
g	Software version	The value given by the applicant to identify a specific revision of the software (including SaMD) (IMDRF)	N
h	Firmware version	The value given by the applicant to identify a specific revision of the firmware (including SaMD) (IMDRF)	N

i	Device manufacturing date	The date of manufacture for the medical device to which this report refers	N
j	Device expiry date	The expiry date for the medical device to which this report refers	N
k	Date when device was implanted	The implant date for the medical device to which this report refers- if exact date is unknown please add timeframe	N
l	Date when device was explanted	The explant date for the medical device to which this report refers- if exact date is unknown please add timeframe	N
m	If precise implant/explant dates are unknown, provide the duration of implantation	How long was the implant in the patient? (months/years)	N
n	Implant facility	The healthcare facility where the device was implanted	N
o	Explant facility	The healthcare facility where the device was explanted	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 fields provided	N
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.)	N
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; For In-House manufactured devices: the date the device was first made available for use and/or put into service. Please indicate to which option the date refers. N.B- single choice	N
2,4	**Risk class of device when placed on market**	Select which regulation the device was conforming to when it was placed on the market, irrespective of when the actual incident occurred	

a	This device has been placed on the market before the implementation of the MDD/AIMDD/IVDD OR MDR/IVDR	Select if the device was placed on the market before the implementation of the MDD (93/42/EEC)/AIMDD (90/385/EEC)/IVDD (98/79/EC) OR MDR (Regulation (EU) 2017/745)/IVDR (Regulation (EU) 2017/746)	Y
b	MDD/AIMDD/IVDD Class	Indicate the relevant Device 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	Y
b	MDR/IVDR 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	Y
2.5a	**Market distribution of device (region/ country) (according to the best knowledge of the manufacturer)**	Indicate which countries the medical device has been distributed to- please fill to the best of your knowledge	Y
2,6	**Use of accessories, associated devices or other devices**		
a	Relevant accessories used with the device being reported on, if applicable	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 CA of the need for a separate MIR form from the other manufacturer(s) involved.	N

b	Relevant associated devices used with the device being reported on, if applicable	Associated devices are those used together/in combination and may or may not be from the same manufacturer as the device being reported on. An example is the use of a CT scanner used in combination with contrast medium; contrast injectors; tubing, syringes etc. Provide as much information as possible, including manufacturer names if different. This field may be used to alert the relevant CA of the need for a separate MIR form from the other manufacturer(s) involved.	N

3.Incident information derived from health care professional and/or user

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	Describe the incident/event including any relevant information that might impact the understanding or evaluation of the adverse event. This should cover the first observable event or possibly a later secondary but more serious event, or maybe both. Describe the condition/outcome of a patient after the event, including the degree of wellness and the need for continuing care, medication, support, counselling, or education.	Y

3,2 Medical device problem information

a	IMDRF Medical device problem codes (annex A)	Please enter the most relevant Level 3 observation on the medical device problem as Choice 1. You may chose up to 5 other different codes that describe the medical device problem. 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. You can propose a new IMDRF code/term. If no code on level 2 can be chosen, select one from level 1 and propose a new IMDRF code/term for levels 2 and 3. The aim is always to code to the most appropriate level. If no code (on any hierarchy level) can be found briefly explain why. (This is a way to propose new IMDRF terms which could be incorporated in the nomenclature during a maintenance session) Note Choice 1 is mandatory after the transitional period. The other codes are optional.	Y
b	Number of patients involved	The number of patients involved . Please note that Patient could also mean user or other third person and the initial reporter may be a family members or other third person.	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. N.B- single choice	Y
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.B- single choice	N

e	Usage of device	Indicate the usage of the device at the time the incident occurred e.g. IVDs need to choose "reuse of a reusable medical device ". Please describe the usage if none of the provided options are applicable select Other and describer. Compassionate / humanitarian use (Medtech Europe to provide further IVD usage examples)	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 explanation of an implanted device; 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

3,3 PATIENT INFORMATION

a	IMDRF health effect codes	Mandatory once transition period is over for using IMDRF 'Clinical signs, symptoms, and conditions codes' (Annex E) and IMDRF 'Health impact' codes (Annex F)". You can choose up to 6 codes to describe: 1) clinical signs, symptoms, conditions and 2) health impact. 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. You can propose a new IMDRF code/term. If no code on level 2 can be chosen, select one from level 1 and propose a new IMDRF code/term for levels 2 and 3. The aim is always to code to the most appropriate level. If no code (on any hierarchy level) can be found briefly explain why. (This is a way to propose new IMDRF terms which could be incorporated in the nomenclature during a maintenance session)	N
b	Age of the patient at the time of 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 and months	N
c	Gender	The gender of the patient involved in this event	N

d	Body Weight (Kg)	The patient's weight in kilograms	N
e	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. Exclude medication taken as a consequence of the incident, i.e. to treat the adverse event	N
3,4	**INITIAL REPORTER (can be healthcare professional of facility, patient, lay user)**		
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
b	Name of the health care facility	The name of 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
c	Healthcare facility report Number	The Report reference number used by the healthcare facility concerned when they reported the incident.	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
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
f	Email	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
g	Phone	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
h	Country	The country of the initial reporter where this event occurred. If this even did not occur in a health care facility put the origin of the country of the report.	Y
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

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
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
l	P.O Box	The P.O 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
m	City name	The name of the city initial reporter If this incident did not occur in a health care facility you don't need to fill out this field	N
n	Postcode	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

4. Manufacturer analysis

4,1 Manufacturer's preliminary comments

a	For initial and follow-up reports: preliminary results and conclusions of manufacturer's investigation	Details of any preliminary analysis you can provide	N
b	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

c	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
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	A report of your analysis of the device involved in this event. 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 emails going back and for the we ask for it 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	Y
b	For Final (Non-reportable incident)- Fill out rationale for why this is considered not reportable	If the incident was deemed not reportable in the first place please indicate here why. You do not have to fill out any other additional fields (Industry to help with examples)	N
c	Is root cause confirmed	Please indicate if there is evidence of a causal link to the medical device problem	Y
d	Has the risks assessment been reviewed?	Indicate if the risk assessment has been reviewed after this incident and provide a rationale why the risk assessment is still adequate or why no review is required	Y

e	IMDRF Cause investigation terms and codes	Please enter the most relevant or most likely lowest level Cause investigation codes as Choice 1 in each section. 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. You can propose a new IMDRF code/term. If no code on level 2 can be chosen, select one from level 1 and propose a new IMDRF code/term for levels 2 and 3. The aim is always to code to the most appropriate level. If no code (on any hierarchy level) can be found briefly explain why. (This is a way to propose new IMDRF terms which could be incorporated in the nomenclature during a maintenance session) Note Choice 1 is mandatory after the transitional period. The other codes are optional.	Y

f	IMDRF Component codes	Please enter the most relevant lowest level component code as Choice 1 in each section. You may chose up to 5 other different codes that describes the component 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. You can propose a new IMDRF code/term. If no code on level 2 can be chosen, select one from level 1 and propose a new IMDRF code/term for levels 2 and 3. The aim is always to code to the most appropriate level. If no code (on any hierarchy level) can be found briefly explain why. (This is a way to propose new IMDRF terms which could be incorporated in the nomenclature during a maintenance session)	N
g	Description of remedial action/corrective action/preventive action / Field Safety Corrective Action	Describe any remedial, corrective and / or preventative action(s) taken as a result of this event and / or your investigation.	Y
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
i	Final comments from the manufacturer on Cause investigation and conclusion	Enter your final comments on this incident for cause investigation and conclusion If you refer to an existing CAPA please provide the reference or identification number of that CAPA	N

4,3 Similar Incidents

4.3.1	**Use of IMDRF terms and codes for identifying similar incidents**		
a	Identification of similar incidents using IMDRF Adverse Event Reporting terms and codes	Incidents occurring with 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 incident is known, or • having the same medical device problem if the investigation finding is unknown; 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 incident data based on the most relevant codes (this should be choice 1 in each coding section). Other - Where the IMDRF 'medical device problem' and 'investigation findings' codes are not used to describe similar incident data, please detail how the similar 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 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 incidents.	Y

4.3.2	**Use of in-house terms/codes for identifying similar incidents (only for transition period)**		
	If similar incident were not identified by IMDRF codes but by in-house codes, please indicate the code / combination of codes below.	Incidents occurring with the same device type/variant of a given manufacturer, and • having the same root cause evaluation and the same medical device problem, if the root cause evaluation of the original incident is known, or • having the same medical device problem if the root cause evaluation 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 incident data based on the most relevant code and term.	Y
a		Other - Where the in-house 'medical device problem' and 'root cause evaluation' terms and codes are not used to describe similar incident data, please detail how the similar 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 incident data based on in-house patient problem terms and codes. This is to be used if the manufacturer decides to use the form for the transitional period (Dec 2018-Dec 2019) and has not yet implemented IMDRF codes. After Dec 2019 this section will not be used as similar incidents will be based on the IMDRF codes.	

4.3.3	**Number of similar incidents and devices on the market**		
a	Indicate on which basis similar incidents were identified regarding the device or device variant	How have you defined and categorised similar incidents? Specify the particular products, batches, serial number range etc that you believe is the most appropriate for categorisation of relevant similar incidents. N.B- single choice	Y
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 cumulative numbers 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). In cases of uncertainties which denominator data should be chosen, please discuss with the coordinating CA i.e. Manufacturers should work with the CA on the most appropriate denominator data for the device (or variant) concerned . In the future this information/guidance may be included in the DSVGs Please use the 'other- describe' if none of the above are suitable For a device that may receive events over its entire service life, the ideal denominator values are the number of remaining active devices within each given time period. However, since most countries do not report in-service and out of service data to manufacturers, provide the all-time cumulative sales from the date of the CE Mark approval to the end date of each given time period instead of within each given time period N.B- single choice	Y

c	Enter the number of similar incidents and devices on the market for the indicated time periods	Enter, for the indicated time periods, the number of similar incidents and number of devices on market (i.e. denominator data should align with 4.3.3.b above). The default time period for similar incident data is yearly unless (a) a different time period has been specified by the European Medical Device Vigilance Experts Group or (b) the device has not been on the European market for more than three years. In the event of (b) please clearly indicate the time periods being used to provide similar incident data. If selecting yearly periods, the first selection will automatically set the other time periods	Y
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
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
c	Number of similar incidents that occurred within each time period:	Indicate the number of similar incidents. If none please add zero (type in "0")	Y
c	Number of devices on market	Indicate the number of devices placed on market or the selected option for the denominator data in section 4.3.3.b. If none please add zero (type in "0") Please select the end of the previous months if data on numbers is not possible up to the date of the incident	Y
c	In country where incident occurred	In the country where the incident occurred. If none please add zero (type in "0")	Y

c	EEA + candidate countries + CH + TR	In EEA + CH + TR. If none please add zero (type in "0") This number will include the number directly above	Y
c	World	In the world. If none please add zero (type in "0") This number will include the number directly above	Y
d	Comments on how similar incidents and associated number of devices on the market were determined	Add any additional information here	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

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 incident There is nothing to be filled out here by the manufacturer

ld is not mandatory please leave blank.

c exchange. For the rest of fields please leave blank if unknown.

nder MDD/AIMDD/IVDD and MDR/IVDR respectively'

Mandatory properties				Comments
Initial	Follow Up	Final (Reportable incident)	Final (Non-reportable incident)	
Y	Y	Y	Y	
N	N	N	N	Will be mandatory as soon as available in EUDAMED
N	Y	Y	Y	
N	N	N	N	Will be mandatory as soon as available in EUDAMED
Y	Y	Y	Y	

Y	Y	Y	Y
Y	Y	Y	Y

Y	Y	Y	Y
Y	Y	N	N

Y	Y	Y	N
Y	Y	Y	Y
Y	Y	Y	Y
N	N	N	N

N	N	N	N	
N	N	N	N	
N	N	N	N	
Y	Y	Y	Y	
Y	Y	Y	Y	
				When available will be mandatory. The full details will be auto filled once SRN is available

Y	Y	Y	Y	Information in c,d, e, f will 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 if possible (as well as the Authorised Representative.)
Y	Y	Y	Y	Information in c,d, e, f will 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 if possible (as well as the Authorised Representative.)

Y	Y	Y	Y	
				Information in c,d, e, f will 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 if possible (as well as the Authorised Representative.)
Y	Y	Y	Y	
				Information in c,d, e, f will 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 if possible (as well as the Authorised Representative.)
Y	Y	Y	Y	
Y	Y	Y	Y	One of either h, i, j, k
N	N	N	N	One of either h, i, j, k
N	N	N	N	One of either h, i, j, k
N	N	N	N	One of either h, i, j, k
Y	Y	Y	Y	
Y	Y	Y	Y	

Y	Y	Y	Y	Mandatory if manufacturer is non EEA, CH, TR
Y	Y	Y	Y	When available will be mandatory. The full details will be auto filled once SRN is available
Y	Y	Y	Y	
Y	Y	Y	Y	
Y	Y	Y	Y	
Y	Y	Y	Y	
Y	Y	Y	Y	
Y	Y	Y	Y	One of either h, i, j, k
N	N	N	N	One of either h, i, j, k
N	N	N	N	One of either h, i, j, k
N	N	N	N	One of either h, i, j, k
Y	Y	Y	Y	
Y	Y	Y	Y	
Y	Y	Y	Y	Only mandatory if Submitter of reporter is 'Other'
Y	Y	Y	Y	Only mandatory if Submitter of reporter is 'Other'
Y	Y	Y	Y	Only mandatory if Submitter of reporter is 'Other'

Y	Y	Y	Y	Only mandatory if Submitter of reporter is 'Other'
Y	Y	Y	Y	Only mandatory if Submitter of reporter is 'Other'
Y	Y	Y	Y	Only mandatory if Submitter of reporter is 'Other'
Y	Y	Y	Y	One of either g, h, i, j
Y	Y	Y	Y	One of either g, h, i, j
N	N	N	N	One of either g, h, i, j
N	N	N	N	One of either g, h, i, j
N	N	N	N	
Y	Y	Y	Y	
Y	Y	Y	Y	default value to be ‘Unknown’ and for MDD/IVD risk class field is not mandatory but for MDR/IVDR risk class field is mandatory. Form will show ‘unknown’ and it is up to the manufacturer to overwrite (or auto populate in Eudamed). Having the field prepopulated with 'unknown' ensures consistency when the actual UDI is unknown. There is potential for error if it is typed in and the auto processing of the report will fail.

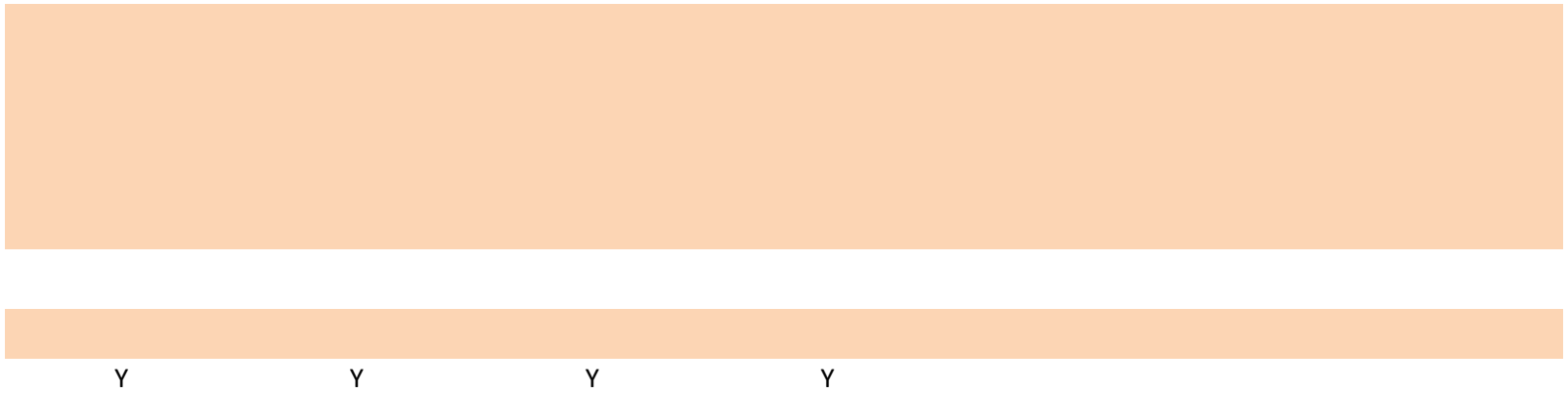
Y	Y	Y	Y	
				default value to be ‘Unknown’ and for MDD/IVD risk class field is not mandatory but for MDR/IVDR risk class field is mandatory. Form will show ‘unknown’ and it is up to the manufacturer to overwrite (or auto populate in Eudamed).Having the field prepopulated with 'unknown' ensures consistency when the actual UDI is unknown. There is potential for error if it is typed in and the auto processing of the report will fail.
Y	Y	Y	Y	
				default value to be ‘Unknown’ and for MDD/IVD risk class field is not mandatory but for MDR/IVDR risk class field is mandatory. Form will show ‘unknown’ and it is up to the manufacturer to overwrite (or auto populate in Eudamed).Having the field prepopulated with 'unknown' ensures consistency when the actual UDI is unknown. There is potential for error if it is typed in and the auto processing of the report will fail.
N	N	N	N	
N	N	N	N	
N	N	N	N	

Y	Y	Y	Y
Y	Y	Y	Y
N	N	N	N
N	N	N	N
N	N	N	N
N	N	N	N
N	N	N	N
N	N	N	N

N	N	N	N	
N	N	N	N	
N	N	N	N	
N	N	N	N	
N	N	N	N	
N	N	N	N	
N	N	N	N	
N	N	N	N	
				Depends on Risk Class in 2.4 - see sheet labelled 'Risk Class and NB properties'
N	N	N	N	
				Depends on Risk Class in 2.4 - see sheet labelled 'Risk Class and NB properties'
N	N	N	N	

Y	Y	Y	Y	
				One of either a,b or c
Y	Y	Y	Y	
				One of either a,b or c
Y	Y	Y	Y	
				One of either a,b or c
N	N	Y	N	
N	N	N	N	

N N N N



Y Y Y Y

Y	Y	Y	Y
			Mandatory once transition period is over
N	N	N	N
Y	Y	Y	Y
N	N	N	N

N	N	N	N
N	N	N	N

N	N	N	N
N	N	N	N
N	N	N	N

N	N	N	N
N	N	N	N
Y	Y	Y	Y
N	N	N	N
N	N	N	N
N	N	N	N
N	N	N	N
N	N	N	N
N	N	N	N
Y	Y	Y	Y
N	N	N	N

N	N	N	N
N	N	N	N
N	N	N	N
N	N	N	N
N	N	N	N

Y	Y	N	N
N	Y	N	N

N	Y	N	N
N	N	Y	N
N	N	N	Y
N	N	Y	N
N	N	Y	N

N	N	Y	N

N	N	N	N
N	N	Y	N
N	N	N	N
N	N	N	N

N	N	Y	N

N N Y N

N	N	Y	N
N	N	Y	N

N	N	Y	N	
N	N	Y	N	
				Only Mandatory if using different dates from calendar years
N	N	Y	N	
				Only Mandatory if using different dates from calendar years
N	N	Y	N	
N	N	Y	N	
N	N	Y	N	

N	N	Y	N
N	N	Y	N
N	N	N	N
N	N	N	N

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

Follow Up	Final (Reportable incident)	Final (Non-reportable incident)
N	Y	N
N	Y	N
N	Y	N
N	Y	N
N	N	N
N	Y (for part “sterile”)	N
N	Y (for part “measuring function”)	N
N	Y (for part "sterile" and part “measuring function”)	N
N	Y	N
N	Y	N
N	Y	N
N	N	N
N	Y	N
N	Y	N
N	Y	N
N	N	N
N	Y	N
N	Y	N
N	Y	N
N	Y	N
N	Y	N
N	Y	N
N	Y	N
N	N	N
N	Y	N

Question	Default status
1.3.1 a free text	disabled
1.3.4 a-l	enabled
2.2 a free text	disabled
2.3 q Year and Month	disabled
2.4 c MDR Type (Multiple choice)	disabled
2.4 c IVDR Type (Multiple choice)	disabled
3.2 c free text	disabled
3.2 d free text	disabled
3.2 e free text	disabled
3.4 a free text	disabled
4.2 d If 'No', rationale for no review required	disabled
4.2 d If the risk assessment has been reviewed, is it still adequate?	disabled
4.3.1 a Annex C (Choice 1)	disabled
4.3.1 a free text	disabled
4.3.2 a Annex C Code/Term	disabled
4.32 a free text	disabled
4.3.3 b free text	disabled

Description
Enabled if "Other, please specify" is selected
Autopopulated if the submitter of the report is a Manufacturer or Authorised representative
Enabled if "Other, please specify" is selected
Enabled if "If software, date first made available" is selected
Enabled if an MDR class is selected. Custom made is always enabled.
Enabled if an IVDR class is selected
Enabled if "Other" is selected
Enabled if "Other, please describe" is selected
Enabled if "Other" is selected
Enabled if "Other, please specify" is selected
Enabled if "No" ("Has the risk assessment been reviewed?") is selected
Enabled if "Yes" ("Has the risk assessment been reviewed?") is selected
Enabled if Annex A (of the same question) is selected
Enabled if "Other" is selected
Enabled if "Code for most relevant medical device problem" (of the same question) is specified
Enabled if "Other" is selected
Enabled if "Other - describe" is selected

Device (bold): For the purpose of this annex A, a **device** means a medical device including accessories and components.

Level 1			Level 2			Level 3		
Term	Definition	Code	Term	Definition	Code	Term	Definition	Code
Patient Device Interaction Problem	Problem related to the interaction between the patient and the **device**.	A01	Patient-Device Incompatibility	Problem associated with the interaction between the patient's physiology or anatomy and the **device** that affects the patient and/or the **device**.	A0101	Biocompatibility	Problem associated with undesirable local or systemic effects due to exposure to medical device materials or leachates from those materials by a patient who has an implant or is receiving treatment with a **device** made from them.	A010101
						Device Appears to Trigger Rejection	The **device** appears to elicit undesired response in the patient to the presence of an implanted or invasive **device**, without inherent **device** failure, e.g. fibrous encapsulation, or inflammation of the tissue around the **device**, or extrusion of the **device**.	A010102
						Inadequacy of Device Shape and/or Size	The physical size and/or shape of the **device** was inadequate with regard to the patient's anatomy.	A010103
			Osseointegration Problem	Problem associated with interconnection between the bone tissue and the implanted **device**.	A0102	Failure to Osseointegrate	Problem associated with the failure to see direct anchorage of an implant by the formation of bony tissue around the implant without the growth of fibrous tissue at the bone-implant interface.	A010201
						Loss of Osseointegration	Problem associated with weakened integration of the **device** at the bone-implant interface due to loss of fibrous and/or bony tissue and leading to compromised anchorage of the device. i.e. 'Loosening/Lysis.' "	A010202
			Loosening of Implant Not Related to Bone-Ingrowth	Problem associated with the loss of direct anchorage of an implanted **device** over time or due to an injury.	A0103			
			Migration or Expulsion of Device	Problem with an implanted or invasive **device** moving within the body, or being completely expelled from the body.	A0104	Expulsion	Problem with all or part of an implanted or invasive **device** being completely expelled from its intended location within the body.	A010401
						Migration	Problem with all or part of an implanted or invasive **device** moving from its intended location within the body.	A010402
Manufacturing, Packaging or Shipping Problem	Problem associated with any deviations from the documented specifications of the **device** that relate to nonconformity during manufacture to the design of an item or to specified manufacturing, packaging or shipping processes (out of box problem).	A02	Product Quality Problem	Problem associated with an inherent **device** characteristic that is not satisfactory as specified or delivered.	A0201	Dull, Blunt	Problem associated with a **device** not being as sharp as intended or expected.	A020101
						Nonstandard device	Problem associated with the **device** that does not meet the specifications or requirements for which it was manufactured (e.g. materials, parts, manufacturing process).	A020102
			Defective Component	Problem associated with a device component having flaws of dimensional deviations greater than acceptable for the intended use.	A0202			
			Defective Device	Problem associated with having flaws or dimensional deviations greater than acceptable for the intended use of the **device**.	A0203			
			Device Damaged Prior to Use	Problem associated with packaging or shipping damage prior to the use of the **device**.	A0204			
			Packaging Problem	Problem associated with the materials used to construct the cover or outer wrapping of the **device**.	A0205	Difficult to Open or Remove Packaging Material	Problem associated with difficulty for users to operate the **device**, specifically as it relates to the opening or removal of the outer wrapping.	A020501

						Incomplete or Missing Packaging	Problem associated with the nonconformance to the **device** specifications due to incomplete or missing packaging that may compromise the **device** operation as intended.	A020502
						Unsealed Device Packaging	Problem associated with the loss of packaging seal.	A020503
						Tear, Rip or Hole in Device Packaging	Problem associated with packaging damage (tear, rip or hole) prior to the use of the **device**.	A020504
			Device Misassembled During Manufacturing / Shipping	A **device** found incorrectly assembled when delivered to the user facility.	A0206	Component Misassembled	A **device** found to have one or more components incorrectly assembled when delivered to the user facility.	A020601
						Component Missing	A **device** component(s) found to be missing when delivered to the user facility.	A020602
			Shipping Damage or Problem	Problem associated with shipping damage or problem prior to the use of the **device**.	A0207	Delivered as Unsterile Product	Problem associated with a **device** being received in such a manner to indicate that its sterility has been compromised (e.g. sterile packaging breached, visible contaminate present)	A020701
Chemical Problem	Problem associated with any from the documented specifications of the **device** that relate to any chemical characterization, i.e., element, compound, or mixture.	A03	Device Emits Odor	Problem associated with an unexpected or inappropriate smell released by the **device**.	A0301			
			Device Ingredient or Reagent Problem	Problem associated with any deviations from the documented specifications of the **device** that relate to any ingredient or reagent characterization.	A0302	Clumping in Device or Device Ingredient	Problem associated with the aggregation of particles into irregular masses.	A030201
						Coagulation in Device or device Ingredient	Problem associated with the undesired characterization of congealing, solidifying, thickening, curdling.	A030202
						Precipitate in Device or device Ingredient	Problem associated with the separation of solid particles from a liquid as the result of a chemical or physical change.	A030203
						Cross Reactivity	Problem associated with the degree to which an antibody or antigen participates in cross reactions.	A030204
						Particulates	Substances that consist of separate particles that are introduced by the **device** during use.	A030205
						High pH	pH higher than expected and / or anticipated.	A030206
						Low pH	pH lower than expected and / or anticipated.	A030207
			Improper Chemical Reaction	Problem associated with an unexpected or incomplete chemical reaction or effect.	A0303			
Material Integrity Problem	Problem associated with any deviations from the documented specifications of the **device** that relate to the limited durability of all material used to construct device.	A04	Break	Problem associated with undesired damage or breakage of those materials used in the **device** construction.	A0401	Fracture	Problem associated with a partial or full-thickness crack in the **device** materials.	A040101
						Loss of or Failure to Bond	Problem associated with lack or loss of adherence between materials intended to be joined together by an adhesive.	A040102
						Material Fragmentation	Problem associated with small pieces of the **device** breaking off unexpectedly.	A040103
						Solder Joint Fracture	Problem associated with undesired damage or breakage in a solder joint of materials used in the **device** construction.	A040104
			Burst Container or Vessel	Problem associated with the pressure inside a vessel or container rising to such a degree that the container ruptures.	A0402			

			Explosion	Problem associated with the violent bursting due to the sudden expansion of air, gas or fluid.	A0403				
			Crack	Problem associated with an undesired partial separation and/or a visible opening along the length or width in the materials that are used in the **device** construction.	A0404				
			Degraded	Problem associated with a undesired change in the chemical structure, physical properties, or appearance in the materials that are used in the **device** construction.	A0405	Calcified	Problem associated with buildup of calcium salts on the **device**.	A040501
						Corroded	Problem associated with the chemical or electrochemical reaction between materials, usually a metal and its environment that produces a deterioration of the metal and its properties.	A040502
						Material Erosion	Problem associated with a progressive loss of a material from a solid surface.	A040503
						Pitted	Problem associated with the corrosion of a material's surface, confined to a point or small area that takes the form of cavities.	A040504
						Flaked	Problem associated with the detachment of small pieces of the coating film of a material.	A040505
						Peeled / Delaminated	Peeling or delamination of composite materials, including coatings, that occurs when layers are separated as a result of stress or impact and resulting in loss of mechanical toughness.	A040506
						Naturally Worn	Problem associated with material damage to a surface, usually involving progressive loss or displacement of material, due to relative motion between that surface and a contacting substance or substances.	A040507
						Unraveled Material	Problem due to the undesired unravelling of material (e.g. disentangled, unwound etc.).	A040508
			Material Deformation	Problem associated with an undesired material change in shape or property caused by external forces.	A0406	Deformation Due to Compressive Stress	Problem associated with an undesired bulge, bend, bow, kink, or wavy condition observed in the **device** material resulting from compressive stresses.	A040601
						Dent in Material	Problem associated with a undesired change in shape, characterized by the presence of a slight hollow (dent) in the **device** surface.	A040602
						Failure to Fold	Problem associated with an undesired material change in physical property, characterized by failure to fold.	A040603
						Failure to Unfold or Unwrap	Problem associated with the comprising materials' deformation in that **device** fails to open its wrapping or open/extend in a certain manner i.e. balloon or lens.	A040604
						Material Frayed	Problem associated with the comprising materials having damaged edges.	A040605
						Material Invagination	Problem associated with an undesired material change in shape, characterized by the infolding of one part within another part of a structure.	A040606
						Material Too Rigid or Stiff	Problem associated with an undesired material change in physical property, characterized by rigidity (it resists deformation in response to an applied	A040607
						Material Too Soft / Flexible	Problem associated with any **device** material that results in the material's inability to maintain the desired shape or support function.	A040608

						Material Twisted / Bent	Problem associated with deformations that lead to twisting or bending of the **device**.	A040609
						Melted	Problem associated with a solid **device** being transformed into a molten or liquid state.	A040610
						Stretched	Problem associated with an increase or elongation in a materials' dimension.	A040611
			Material Discolored	Problem associated with an undesired streak, pattern and/or a noticeable change in color from the rest of the materials used in the **device** construction.	A0407			
			Material Disintegration	Problem associated with material breaking into small particles.	A0408			
			Material Opacification	C62895; FDA 1426 - Problem associated with an undesirable opaqueness or cloudiness.	A0409			
			Material Perforation	Material constituting device is perforated possibly compromising the **device**'s intended purpose.	A0410	Material Puncture / Hole	**Device** material(s) punctured leading to undesired holes/openings.	A041001
			Material Protrusion / Extrusion	Problem associated with undesired physical appearance of **device** material, specifically when material extends beyond or above **device** surface.	A0411			
			Material Rupture	Problem associated with perforations that lead to bursting of the **device**.	A0412			
			Material Separation	Problem associated with an undesired disassociation or breaking apart of the **device**.	A0413			
			Material Split, Cut or Torn	Problem associated with materials consisting the **device** are split, cut or torn due to external forces (e.g. wrenching or laceration) or internal forces (e.g. exceeding the tensile stress limits belonging to the materials used in the **device** construction).	A0414			
			Scratched Material	Problem associated with an undesirable shallow cut or narrow groove in the surface of the **device** materials.	A0415			
Mechanical Problem	Problems associated with mechanical actions or defects, including moving parts or subassemblies, etc.	A05	Detachment of Device or device Component	Problem associated with the separation of the **device** from its physical construct, integrity, or chassis.	A0501			
			Device Damaged by Another Device	Problem associated with one **device** causing harm to another **device**.	A0502			
			Ejection Problem	Problems associated with the inability of or unexpected removal or separation of the **device** from its physical location.	A0503	Failure to Eject	Problem associated with the inability to remove or discharge the **device** from the location of use.	A050301
						Unintended Ejection	Problem associated with unexpected discharge of the **device** from expected location includes but not limited to the **device** such as clip appliers, film cartridge, staples.	A050302
			Leak / Splash	Problem associated with the escape of a liquid or gas from the vessel or container in which it is housed.	A0504	Fluid Leak	Escape (Release, Discharge) of fluid through an unintended location - often accompanied by a loss of pressure and/or output.	A050401
						Gas Leak	Problem associated with the unintended escape of a gas from the container in which it is housed.	A050402
						Gel Leak	Escape (Release, Discharge) of gel through an unintended location - as in leakage of ultrasound gel. Escape or release of gel from containment structures - as in gel filled implant leak.	A050403
						Radiation Leak	Escape of radiation (energy in the form of waves or subatomic particles, especially those that cause ionization) through containment structures, leading to unintended exposure.	A050404
						Perivalvular Leak	Problem associated with the escape of blood around a heart valve, particularly around its leaflets.	A050405

			Firing Problem	Problem associated with the **device** not discharging as intended.	A0505	Failure to Fire	Problem associated with failure of the **device** to discharge its load (e.g. surgical stapler failed to partially or completely deploy its staples).	A050501
						Misfire	Problem associated with a therapy or algorithm not being delivered or executed at the expected time.	A050502
			Mechanical Jam	The motion of the **device** is prevented or restricted.	A0506			
			Mechanics Altered	Problem associated with a **device** mechanical functioning of machinery, moving parts or tools of device being changed or modified.	A0507	Failure to Align	Problem associated with a circuit, equipment, or system whereby its functions fail to be properly synchronized or its relative positions properly oriented.	A050701
						Failure to Cut	Inability of the **device** to make an incision, pierce or open as intended.	A050702
						Failure to Cycle	Problem associated with the **device** failing to complete a series of processes or events.	A050703
						Failure to Form Staple	Problem associated with the **device** failing to connect tissue with a stapling device due to the staples not forming correctly.	A050704
			Noise, Audible	Problem associated with any unintended sound which emanates from the **device** (for example, squeaking from two parts rubbing together or buzzing sounds from electrical components).	A0508			
			Physical Resistance / Sticking	Problem associated with the lack of movement in the **device** due parts sticking or seizing.	A0509			
			Retraction Problem	Problem associated with drawing back the **device** to an intended location.	A0510			
			Structural Problem	Problem associated with the basic physical construction or physical make up of the **device**.	A0511	Collapse	Problem associated with the buckling or crushing of material from external forces.	A051101
						Sharp Edges	The **device** has undesirable sharp edges which can cause harm or damage.	A051102
						Difficult to Fold or Unfold	Problem associated with the use of the **device** in terms of user experiencing difficulty to close or to spread out/extend length of the **device**, even if the operation is being performed according to labeled instructions for use.	A051103
						Difficult to Open or Close	Problem associated with the use of the **device** in terms of user experiencing difficulty opening and closing the **device**, even if the operation is being performed according to labeled instructions for use.	A051104
						Incomplete Coaptation	Problem associated with the heart valve leaflet not closing properly.	A051105
			Unintended Movement	Problem associated with an undesired movement of the **device**, which may be related to the **device**- malfunction, misdiagnosis, or mistreatment.	A0512	Device Dislodged or Dislocated	Problems associated with the **device** not remaining in an expected location.	A051201
						Device Tipped Over	Problem associated with the inability of the **device** to stay in an upright position.	A051202
						Device Fell	Problem associated with the **device** or a component unexpectedly being dropped or moving down from an intended place.	A051203
						Device Slipped	Problem associated with the **device** moving or sliding from the intended position.	A051204
						Unintended Collision	Problem associated with the **device** impacting with another object.	A051205
						Unintended System Motion	Problem associated with any motion of the system or components that was not initiated by the user.	A051206
						Unstable	Problem associated with the mechanical stability of the **device**.	A051207
						Vibration	Problem associated with the undesirable mechanical oscillation.	A051208

Optical Problem	Problem associated with transmission of visible light affecting the quality of the image transmitted or otherwise affecting the intended application of the visible light path.	A06	Misfocusing	The problem relates to the poor focusing of the object or the focus is on the wrong object or in the wrong area.	A0601			
			Optical Decentration	Problem associated with being off-center of optical lenses.	A0602			
			Optical Discoloration	Problem associated with an undesired change of color.	A0603			
			Optical Distortion	Problem associated with an optical defect in an image-forming system whereby the image is not the shape of an ideal image of the object.	A0604			
			Optical Obstruction	Problem associated with the blocking of optical devices, e.g. visual pathways.	A0605			
Electrical /Electronic Property Problem	Problem associated with a failure of the electrical circuitry of the **device**.	A07	Capturing Problem	Problem associated with the inability of the **device** to achieve successful depolarization and contraction of a cardiac chamber caused by a pacemaker output pulse.	A0701	Failure to Capture	Problem associated with the failure to achieve effective and consistent depolarization of the heart resulting from the electrical stimulus of the pacemaker.	A070101
						High Capture Threshold	Problem with the amount of output energy needed to cause cardiac depolarization being higher than expected/desired.	A070102
						Intermittent Capture	Problem associated with the ineffective and inconsistent depolarization of the heart.	A070103
						Unstable Capture Threshold	Problem with the amount of output energy needed to cause cardiac depolarization being unstable.	A070104
			Continuous Firing	Problem associated with the excessive production of electrical impulses over a period.	A0702			
			Arcing	Problem associated with electrical current flowing through a gap between two conductive surfaces, typically resulting in a visible flash of light.	A0703	Arcing at Paddles	Problem associated with electrical current flowing through a gap between paddles (conductive surfaces), typically resulting in a visible flash of light.	A070301
						Arcing of Electrodes	Problem associated with electrical current flowing through a gap between electrodes (conductive surfaces), typically resulting in a visible flash of light.	A070302
			Sparking	Problem associated with a flash of light related to an electrical discharge into a normally non conductive medium, such as air. Not associated with a discharge between two conductive surfaces.	A0704			
			Battery Problem	Problem associated with the internal power of the **device** (e.g. battery, transformer, fuel cell or other power sources).	A0705	Battery Problem: High Impedance	Problem related to increased battery internal impedance.	A070501
						Battery Problem: Low Impedance	Problem related to decreased battery internal impedance.	A070502
						Failure to Run on Battery	Problem associated with the **device** failing to operate when not connected to a fixed power source.	A070503
						Premature Discharge of Battery	Battery discharging earlier than expected.	A070504
			Charging Problem	Problem associated with the inability of the **device** to successfully charge an electrical source.	A0706	Aborted Charge	Problem associated with the premature ending of the charging process (e.g. of a battery or other charge storage device).	A070601
						Delayed Charge Time	Problem associated with an unexpected amount of time required to charge the **device** (e.g. a delay in starting charging or a longer than expected charge time).	A070602
						Failure to Charge	Problem associated with inability to initiate the appropriate charging process (e.g. of a battery or other charge storage device)	A070603
			Failure to Discharge	Problem associated with the failure of a battery or other charge storage device to appropriately discharge as intended. Does not apply to defibrillation.	A0707			

			Power Problem	Problem associated with the energy to operate the **device**.	A0708	Complete Loss of power	Problem associated with the lack of power to run the **device**.	A070801
						Intermittent loss of power	Problem associated with an intermittent disruption to the power to run the **device**.	A070802
						Failure to Power Up	Problem associated with the inability of the **device** to turn on related to energy delivered to the **device**.	A070803
						Unintended power up	Problem associated with the **device** turning on when not intended.	A070804
			Device Sensing Problem	Problem associated with the **device** feature that are designed to respond to a physical stimulus (temperature, illumination, motion, cardiac rhythms) and that do not transmit a resulting signal for interpretation or measurement.	A0709	Decreased Sensitivity	Problem with the **device** being less sensitive to an input than intended or expected.	A070901
						Increased Sensitivity	Problem with the **device** being more sensitive to an input than intended or expected.	A070902
						Failure to Analyze Signal	Problem with the **device** not analyzing a signal.	A070903
						Failure to Select Signal	Problem associated with the failure of the **device** to select the appropriate input signal.	A070904
						High Sensing Threshold	Problem associated with the amount of input required by the **device** to detect a signal being higher than expected/desired.	A070905
						Low Sensing Threshold	Problem associated with the amount of an input required by the **device** to detect a signal being lower than expected/desired.	A070906
						Loss of Threshold	Problem associated with the loss of the minimum amount of energy, voltage, or current needed to consistently stimulate the heart muscle.	A070907
						Failure to Sense	Problem associated with the failure of the **device** designed to respond to a physical stimulus (as temperature, illumination, motion) to transmit a resulting signal for interpretation or measurement.	A070908
						Over-Sensing	Problem related to failure of the **device** to properly filter cardiac signals resulting in inappropriate device response.	A070909
						Under-Sensing	Problem related to failure of the **device** to properly detect intrinsic cardiac activity and respond appropriately.	A070910
						Sensing Intermittently	Problem with the **device** receiving an incoming signal on an intermittent basis when expected to be continuous.	A070911
						Incorrect Interpretation of signal	Problem with the **device** inappropriately analyzing a signal.	A070912
			Failure to Conduct	Problem associated with the inability of the **device** to allow a current of electricity to pass or to conduct electricity continuously along an electrical path.	A0710			
			Interrogation Problem	Problems associated with the **device**'s ability to respond to signals from a system designed to interrogate its status.	A0711	Difficult to Interrogate	Problem associated with difficulty of a transponder system to trigger a response.	A071101
						Failure to Interrogate	Problem associated with the **device** failure to appropriately respond to signals from a system designed to interrogate its status.	A071102
			Pacing Problem	Problem associated with the inability of the **device** to generate a therapeutic simulated heart beat via electrical impulses.	A0712	Failure to Convert Rhythm	Failure of the **device** therapy or set of therapies to terminate the harmful cardiac rhythm that the therapy is meant to terminate.	A071201
						Inaccurate Synchronization	Problem associated with an error due to imperfect timing of two operations, e.g. signal transmission time.	A071202

						Inappropriate waveform	Failure of the **device** to generate a correctly-shaped pacing output, e.g., a waveform that is too wide.	A071203
						No Pacing	Problem associated with the **device** ceasing to deliver paces.	A071204
						Pacemaker Found in Back-Up Mode	A **device** with a pacing function found in back-up Mode. This may be an appropriate fail-safe action (e.g. end of battery life), or be caused by **device**-malfunction or due to operator error.	A071205
						Pacing Asynchronously	Problem associated with a pacing transmission process such that between any two significant instants in the same group, there is always an integral number of unit intervals. Between two significant instants located in different groups, there are not always an integral number of unit intervals.	A071206
						Pacing Inadequately	Pacing voltage or pulse width is less than desired.	A071207
						Pacing Intermittently	Problem associated with the failure of pacing device for a limited period of time, following which the item recovers its ability to perform its required function without being subjected to any external corrective action. Note: such as failure is often recurrent.	A071208
						Pocket Stimulation	Problem associated with a pocket of skin in which the pulse generator is housed.	A071209
			Defibrillation Problem	Problem associated with the inability of the **device** to provide an appropriate or successful electrical shock.	A0713	Failure to Deliver Shock	Problem associated with the failure of the **device** to deliver electrical energy intended to change an electrical rhythm.	A071301
						Inappropriate Shock	Problem associated with the inappropriate delivery of an electrical energy.	A071302
						Intermittent Shock	Problem associated with the failure to deliver shock for a limited period of time, following which the item recovers its ability to perform its required function without being subjected to any external corrective action. Note: such as failure is often recurrent.	A071303
			Unintended Electrical Shock	The **device** delivers unintended electrical shock. Unintended defibrillation shock should be coded as "Inappropriate Shock" code number A071302.	A0714			
			Grounding Malfunction	Problem associated with the inability to connect conductors of an electronic system for the purpose of controlling or impeding ground currents and voltages.	A0715			
			Electrical Overstress	Problem associated with an electrical activity that exceeded the specified threshold limit of the internal integrated circuitry.	A0716			
			Electro-Static Discharge	Problem associated with the discharge of electricity between two bodies previously electrically charged.	A0717			
			Failure to Shut Off	Problem associated with the **device** not powering off when a shut down was requested.	A0718	Device Remains Activated	Problem associated with the **device** continuing to be in an active state after deactivation was requested.	A071801
			Unexpected Shutdown	Problem associated with the **device** unexpectedly powering down.	A0719			
			Electromagnetic Compatibility Problem	Problem associated with the ability of a system to function in its electromagnetic environment without introducing intolerable disturbances to anything in its environment.	A0720	Electromagnetic Interference	Problem associated with a measure of electromagnetic radiation from equipment.	A072001
						Radiofrequency Interference (RFI)	Problem associated with the degradation of the reception of a wanted signal caused by RF disturbance.	A072002

			Circuit Failure	Problem associated with a failure of the internal network paths or electrical circuitry (i.e. electrical components, circuit boards, wiring)	A0721	Capacitative Coupling	Problem associated with the transfer of energy within an electrical network by means of the capacitance between circuit nodes. It occurs when energy is coupled from one circuit to another through an electric field.	A072101
						Electrical Shorting	Problem associated with an electric current travelling along an accidental path (unintended path) in a circuit.	A072102
						Intermittent Continuity	Problem associated with intermittent faults in electrical/electronic interconnections.	A072103
			Impedance Problem	Problem associated with electrical impedance levels between **device** and patient connections.	A0722	High impedance	Problem associated with higher than intended electrical impedance levels between-**device** and patient connections.	A072201
						Low impedance	Problem associated with lower than intended electrical impedance levels between **device** and patient connections.	A072202
Calibration Problem	Problem associated with the operation of the **device**, related to its accuracy, and associated with the calibration of the **device**.	A08	Failure to Calibrate	Problem associated with the failure of the **device** to perform a self-calibration procedure or process designed to assure the accuracy and proper performance of the **device**.	A0801			
			Failure to Recalibrate	Problem associated with the failure of the **device** which is unable to regain a standard level of accuracy when performing a calibration procedure or process designed to assure the accuracy and proper performance of the **device**.	A0802			
			Imprecision	Problem associated with the **device** providing imprecise measurements when compared to a reference standard.	A0803			
			Overcorrection	Problem associated with an adjustment that surpasses a set of criteria.	A0804			
Output Problem	Problem associated with any deviation from the documented specifications of the **device** that relate to the end result, data, or test results provided by the **device**.	A09	Audible Prompt / Feedback	Problem with any deviation from the documented specifications of the **device** that relate to audible feedback. e.g. voice prompts or beeps, but not safety related alarms which are covered under "Protective Measures Problem".	A0901	Inappropriate Audible Prompt / Feedback	Problem with audible messages which do not guide a **device** user to the correct action.	A090101
						Inaudible or Unclear Audible Prompt / Feedback	Problem associated with audible prompts which cannot be heard clearly.	A090102
						No Audible Prompt / Feedback	Problem associated with the **device** ceasing to provide audible prompts.	A090103
			Display or Visual Feedback Problem	Problem with any deviation from the documented specifications of the **device** that relate to visual feedback. e.g. the display of information, images on a screen, or output from the **device**.	A0902	Device Displays Incorrect Message	Problem associated with providing incorrect display information.	A090201
						Display Difficult to Read	Problem associated with legibility of the display, compromising for instance the reading/interpretation of patient parameters or test results. Legibility problems can be due to color, size of font, display screen contrast or other factors.	A090202
						Erratic or Intermittent Display	A **device** does not consistently display the same message, result, reading, or image. e.g. the display might flicker, switch between readings or messages, or go completely blank for brief periods of time.	A090203
						Image Display Error / Artifact	Problem with image display leading to corrupted images or readouts/measurement indications.	A090204
						Image Orientation Incorrect	Problem associated with an incorrect image orientation on the **device** display.	A090205

							No Display / Image	Problem associated with the absence of display or image.	A090206
							No Visual Prompts / Feedback	Problem associated with the **device** ceasing to provide visual feedback.	A090207
							Poor Quality Image	Inadequate quality of an image or any visual representation displayed by the **device**, or output from the **device**.	A090208
							Visual Prompts will not Clear	Problem with visual messages which continue to be displayed on / by the **device** after the appropriate action has been taken.	A090209
				Tactile Prompts / Feedback	Problem with any deviation from the documented specifications of the **device** that relate to tactile feedback. e.g **device** vibrational prompt.	A0903	Inappropriate Tactile Prompt / Feedback	Problem with tactile feedback which does not guide a **device** user to the correct action.	A090301
							No Tactile Prompts / Feedback	Problem associated with the **device** ceasing to provide tactile feedback.	A090302
				Energy Output Problem	Problem with the **device**'s intended output of energy.	A0904	Energy Spectrum Incorrect	Problem associated with the energy output from the **device** not being in the expected part of the spectrum.	A090401
							Failure to Deliver Energy	Problem associated with the failure of the **device** to deliver any energy.	A090402
							Intermittent Energy Output	Problem associated with the energy output from the **device** being inconsistent over time.	A090403
							Output above Specifications	Device output is exceeding the documented specifications of the **device**.	A090404
							Output below Specifications	Device output is below the documented specifications of the **device**.	A090405
							Therapeutic or Diagnostic Output Failure	Problem associated with the failure of the **device** to deliver the output required for treatment or identification of a disease.	A090406
							Therapy Delivered to Incorrect Body Area	Problem associated with the **device** causing unintended therapeutic action to an area of the body other than the intended area.	A090407
				Radiation Output Problem	Problem with the **device**'s intended output of radiation.	A0905	Radiation Output Failure	Problem associated with the absence of radiation output from radiological or diagnostic devices.	A090501
							Radiation Overexposure	Problem associated with excessive radiation emitted from radiological or diagnostic devices.	A090502
							Radiation Underexposure	Problem associated with too little radiation emitted from radiological or diagnostic devices.	A090503
							Unexpected/Unintended Radiation Output	Device-emitted radiation when it was not supposed to. This applies to devices which are intended to emit radiation, and the radiation being emitted from the correct part of the **device**, but at an incorrect time. Use "radiation leak" if the **device** emits radiation which should never have been emitted, or from a location from which it should never be emitted.	A090504
				Gas output problem	Problem associated with gas output.	A0906			
				No Device Output	Problem associated with no measurement outcome, value or data obtained from the **device**.	A0907			
				Incorrect, Inadequate or Imprecise Result or Readings	Problem associated with a nonconforming end result, data, or test results provided by the **device** to its performance specifications.	A0908	Signal Artifact	Problem associated with impurities or interference in a signal (e.g. ECG artifact).	A090801
							Failure to Obtain Sample	The **device** does not collect or transfer the sample.	A090802
							False Negative Result	Problem associated with the **device** incorrectly reporting that something has not been detected and may mislead the operator into not taking certain actions when action should be taken.	A090803

						False Positive Result	Problem associated with the **device** incorrectly reporting that something has been detected and may mislead the operator to take certain actions.	A090804
						Incorrect Measurement	Measurement obtained from or provided by the **device** is obviously incorrect.	A090805
						Non Reproducible Results	**Device** results cannot be reliably reproduced.	A090806
						High Readings	Reading provided by the **device** is too high or higher than expected.	A090807
						Low Readings	Reading provided by the **device** is too low or lower than expected.	A090808
						High Test Results	Test results provided by the **device** are too high or higher than expected.	A090809
						Low Test Results	Test results provided by the **device** are too low or lower than expected.	A090810
						Unable to Obtain Readings	The **device** does not provide or display a valid reading.	A090811
						Missing Test Results	Problem associated with the results of a test or measurement not appearing.	A090812
			Unexpected Therapeutic Results	Problem associated with the use of the **device** for therapeutic purposes.	A0909			
Temperature Problem	Problem associated with the **device** producing unintended temperatures.	A10	Excessive Cooling	Problem associated with the **device** producing temperatures that are lower than specified.	A1001			
			Excessive Heating	Problem associated with the **device** which have a warming or heating function, producing excessive heat.	A1002			
			Insufficient Cooling	Problem associated with the **device** insufficiently cooled in device active (working) or/and non-active (nonworking) state.	A1003			
			Insufficient Heating	Problem associated with the **device** or its components producing temperatures that are not as high as what is specified.	A1004			
			Overheating of Device	Problem associated with the **device** producing high temperatures, such that its operation is compromised or harm is caused (e.g. overheating that produces melting of components or automatic shutdown).	A1005			
			Thermal Decomposition of Device	Problems associated with a discoloration or destruction as a result of thermal decomposition of the **device**.	A1006			
			Fire	Problem associated with the combustion of the **device** with a steady flame.	A1007			
			Flare or Flash	Problem associated with **device**-related burn with an unsteady flame.	A1008			
			Smoking	Problem associated with a cloud of vapor or gas generated from the **device**, generally associated after a fire or a burn.	A1009			
Computer Software Problem	Problem associated with written programs, codes, and/or software system that affects device performance or communication with another device.	A11	Application Network Problem	Problem associated with the deviations from documented system specifications that affects overall system performance and/or the performance of an individual **device** connected to that system.	A1101			
			Application Program Problem	Problem associated with the requirement for software to fulfill its function within an intended use or application.	A1102	Application Program Freezes, Becomes Nonfunctional	Problem associated with freezing and becoming nonfunctional of an application program.	A110201
						Application Program Problem: Dose Calculation Error	Problem associated with the written program code or application software used by the **device** to calculate specific measurements or quantities managed by the **device**.	A110202
						Application Program Problem: Medication Error	Event in which the **device** software results in errors of medication preparation or administration.	A110203

						Application Program Problem: Parameter Calculation Error	Problem associated with the written program code or application software used by the **device** to calculate parameters other than those related to dose or power.	A110204
						Application Program Problem: Power Calculation Error	Problem associated with the written program code or application software used by the **device** for calculations related to **device** power.	A110205
						Application Program Version or Upgrade Problem	Problem associated with installing updates to a software system that affects the **device** performance or communication with another **device**.	A110206
						Problem with Software Installation	Problem associated with installing the **device** software in a manner that allows full functioning of the **device**. Source of installation could be manufacturer or user.	A110207
						Unintended Application Program Shut Down	Problem associated with an unintended shut down by malfunction of the application program.	A110208
			Program or Algorithm Execution Problem	Problem associated with execution problems relating to program or algorithm.	A1103	Delayed Program or Algorithm Execution	Problem associated with delayed execution relating to program or algorithm.	A110301
						Intermittent Program or Algorithm Execution	Problem associated with intermittent execution relating to program or algorithm.	A110302
						Program or Algorithm Execution Failure	Problem associated with the failure of a program or algorithm to execute. Sudden/unexpected interruption to a program's execution.	A110303
			Computer Operating System Problem	Problem associated with software, firmware, and/or hardware elements that control the execution of computer programs and provides such services as computer resource allocation, job control, input/output control, and file management in a computer system.	A1104	Operating System Becomes Nonfunctional	Problem associated with malfunction of the computer operating system as opposed to an application software problem.	A110401
						Operating System Version or Upgrade Problem	Problem associated with replacing an older operating system to an up-to-date operating system.	A110402
			Computer System Security Problem	Problem associated with unauthorized access to or modification of a software system resulting in a loss of confidentiality, integrity, or availability of written program code, application software, or data or entire device.	A1105	Application Security Problem	Problem associated with the acquisition of computer programming codes that can replicate and spread from one computer system to another thereby leading to damaged software, hardware and data.	A110501
						Unauthorized Access to Computer System	Problem associated with an access that was not permitted to the computer system that may lead to modification of program, corruption of data, or and break in network security. This concept is closely associated with computer integrity which is the degree to which a system or component prevents unauthorized access to, or modification of, computer programs or data.	A110502
			Data Back-Up Problem	Problems relating to a system, component, file, procedure, or person available to replace or help restore a primary item in the event of a failure or externally caused disaster.	A1106	Failure to Back-Up	Problem associated with the inability to backup or to retrieve a backed up version (corrupted file) of **device** data or system files.	A110601
						Failure to Convert to Back-Up	Problem associated with a failure to transition from a primary system, component, file, procedure to a backup in response to a failure in the primary item.	A110602
			Data Problem	Event in which data (charting, orders, results) is not correctly stored, transferred, updated, or displayed.	A1107	Loss of Data	Event in which data is unintentionally permanently or temporarily lost, deleted, corrupted, or overwritten.	A110701
						Patient Data Problem	Event in which data is accessed by the healthcare provider and either the wrong patient or the wrong data is retrieved despite correct inquiry procedures.	A110702

			Date/Time-Related Software Problem	Problem associated with programming of calendar dates and/or time as a factor in the operation of the **device**.	A1108			
Connection Problem	Problem associated with linking of the **device** and/or the functional units set up to provide means for a transfer of liquid, gas, electricity or data.	A12	Blocked Connection	Problem associated with linking of the **device** whereby their functional units set up to provide means for a transfer of fluid, gas, or data is prevented or impeded.	A1201			
			Decoupling	Problem associated with the **device** being unassociated in such a way that fluid, gas, power or signal information may not be transferred from one to another.	A1202			
			Disconnection	Problem associated with the linking of the **device** having a sufficient open space to prevent gas, liquid or electrical current flow between connectors.	A1203			
			Failure to Disconnect	Problem associated with the linking of the **device** whereby termination of the transfer of liquid, gas, electricity, or information cannot be accomplished, or linking components do not come apart, or disconnect, when expected.	A1204			
			Loose or Intermittent Connection	Problem associated with the connection of the **device** being loose or intermittent.	A1205			
			Misconnection	Problem associated with the connection of the **device** being improper or not in accordance with device specification, requirements or intended uses.	A1206			
			Incomplete or Inadequate Connection	Problem associated with a partial linking of the **device** whereby device may appear to be connected however only a partial, intermittent or no transfer of liquid, gas, electricity, or information can be accomplished.	A1207			
			Fitting Problem	Problem associated with the connection of the **device** whereby channels, switching systems, and other functional units set up to provide means for a transfer of liquid, gas, electricity, or information do not match or fit.	A1208			
Communication or Transmission Problem	Problem associated with the **device** sending or receiving signals or data. This includes transmission among internal components of the **device** to which the **device** is intended to communicate.	A13	Failure to Read Input Signal	Problem associated with a failure of the **device** to read a signal for interpretation or measurement.	A1301			
			Failure to Transmit Record	Problem associated with a failure of the **device** to transmit a record for interpretation or measurement.	A1302			
			Intermittent Communication Failure	Inconsistent or lack of intended communication of data among internal components or with other external devices.	A1303			
			Telemetry Discrepancy	Problem associated with variability of the transmission of telemetry signals.	A1304			
			Wireless Communication Problem	Problems with the RF wireless technology characteristics and performance (e.g., frequency, output power, range, reception), wireless quality of service, wireless coexistence, security of wireless signals and data, and electromagnetic compatibility.	A1305			
Infusion or Flow Problem	Problem associated with the **device** failing to deliver liquids or gases as intended (e.g. delivering drugs at incorrect rate, Problems with drawing fluid from a system.)	A14	Deflation Problem	Problem associated with the inability of the **device** to release its contents.	A1401			
			Excess Flow or Over-Infusion	Problem associated with a delivery overdose of therapeutic agents, such as drugs or fluids being delivered into a **device** or a patient.	A1402			

			Filling Problem	Problem associated with the method or amount of time associated with the delivery of a fluid. Time to delivery or amount of delivered entity may be affected.	A1403	Inability to Auto-Fill	Complete failure to fill as part of an automated process. For insufficient filling use "Short Fill". For excessive filling use "Overfill". For inconsistent filling use "Volume Accuracy Problem".	A140301
						Overfill	Excessive filling of a **device**. For complete failure to fill use "inability to auto-fill". For insufficient filling use "Short Fill". For inconsistent filling - use "Volume Accuracy Problem".	A140302
						Short Fill	Insufficient filling of a **device**. For complete failure to fill use "inability to auto-fill". For insufficient filling use "short fill". For inconsistent filling - use "Volume Accuracy Problem".	A140303
						Volume Accuracy Problem	Inconsistent filling of a **device**. This describes a problem which is observed to vary between overfilling and under filling, and may be intermittent. Use "Overfill" or "Short Fill" if problem is consistent.	A140304
			Filtration Problem	Problem associated with the process of passing a substance through a porous medium, e.g., a blood clot filter for the removal of suspended matter.	A1404	Inadequate Filtration Process	Problem associated with the filter failing to remove items or substances which should have been removed.	A140401
						Inadequate Ultra Filtration	Problem associated with the transfer of fluid between the blood and dialysate through the dialysis membrane due to a pressure gradient (trans-membrane pressure) existing between the blood and dialysate compartments.	A140402
			Improper Flow or Infusion	Problem associated with the regulation and delivery of therapeutic agents (e.g. air, gas, drugs or fluids into a **device** or a patient under positive pressure).	A1405	Backflow	Continuous flow of fluid (e.g. liquid, gas) against the intended flow direction.	A140501
						Free or Unrestricted Flow	Problem associated with uncontrolled flow of infusion of air, gas or fluids.	A140502
						Gradient Increase	Problem associated with the increased rate of change in temperature, pressure, or other variables as a function of distance, time, etc.	A140503
						Inaccurate Delivery	Delivery at endpoint not as intended; either too low or too high.	A140504
						Inaccurate Flow rate	Problem associated with fluctuations in the flow volume delivered per time, even if end volume is correct, and delivered in the correct total time.	A140505
						Intermittent Infusion	Problem associated with the infusion not being stead-characterised by intermittent stoppages to the flow.	A140506
						Reflux within Device	Problem associated with partial backflow, compromising the **device**'s flow output.	A140507
						Restricted Flow rate	Problem associated with flow rate. Flow volume delivered over time is not reaching intended flow rate.	A140508
						Tidal Volume Fluctuations	Problem associated with the amount of gas that is inspired and expired during one respiratory cycle.	A140509
			Inflation Problem	Problem associated with the inability of the **device** to expand or enlarge with the intended inflation agent (e.g. saline or air).	A1406			
			Insufficient Flow or Under Infusion	Problem associated with an insufficient dose of therapeutic agents, e.g., drugs or fluids being delivered into a patient under positive pressure.	A1407			
			No Flow	Problem arising from the **device** failing to deliver the specified liquid or gas.	A1408	Failure to Deliver	Failure (=complete nonperformance) with regard to the intended function of delivery.	A140801

						Failure to Infuse	Failure (=complete nonperformance) with regard to the intended function of infusion.	A140802
						Inability to Irrigate	Failure (=complete nonperformance) with regard to the intended function of irrigation.	A140803
			Obstruction of Flow	Problem related to an obstruction or blockage within the device component (e.g. tube, opening, pipe) that results in restriction of flow.	A1409	Complete Blockage	Problem related to an obstruction or blockage within the device component (e.g. tube, opening, pipe) that results in no flow.	A140901
						Partial Blockage	Problem related to an obstruction or blockage within the device component (e.g. tube, opening, pipe) that results in a reduction of the flow rate.	A140902
			Difficult to Flush	The **device** is difficult to flush, possibly indicating an obstruction within device.	A1410			
			Pressure Problem	Problem associated with the application of a force either internal or external to device that compromises the flow of fluid or gas.	A1411	Decrease in Pressure	Unintended decrease in pressure, compromising the **device**'s intended function.	A141101
						Increase in Pressure	Unintended increase in pressure, compromising the **device**'s intended function.	A141102
						No Pressure	Unintended complete loss of pressure, compromising the **device**'s intended function.	A141103
			Pumping Problem	Problem associated with pump performance deviating from specifications in a way to compromise flow or infusion.	A1412	Decreased Pump Speed	Unintended decrease in pump speed and hence, probably, flow rate, compromising the intended function of the **device**.	A141201
						Increased Pump Speed	Unintended increase in pump speed and hence, probably, flow rate, compromising the intended function of the **device**.	A141202
						Failure to Pump	Problem associated with the **device** which fails to start pumping.	A141203
						Pumping Stopped	Unexpected /unintended cessation of pump.	A141204
			Suction Problem	Problem associated with suction equipment, which may be a manual, electrical, vacuum or pressure source operated to evacuate and remove undesired substances (air, gas, fluid, or particulates) via tubing and collection bag.	A1413	Decrease in Suction	Problem associated with the removal of fluid or gas from a body cavity due to decreased suction.	A141301
						Increase in Suction	Problem associated with the removal of excess fluid or gas from a body cavity due to increased suction.	A141302
						Suction Failure	Problem associated with the complete inability to provide suction.	A141303
			Priming Problem	Problem associated with the preparation of the **device** to begin pumping.	A1414	Failure to Prime	Problem associated with the **device** failing to begin the priming process (i.e. the process of preparation of device for the delivery of fluids).	A141401
						Incomplete or Inadequate Priming	Problem associated with not adequately preparing the **device**.	A141402
Activation, Positioning or Separation Problem	Problem associated with any deviations from the documented specifications of the **device** that relate to the sequence of events for activation, positioning or separation of device. NOTE 1 “Deployment” is synonymous with “activation”.	A15	Activation Problem	Problem associated with the activation of the **device**.	A1501	Activation Failure Including Expansion Failures	Problem associated with the **device** failing to be activated including expansion.	A150101
						Difficult or Delayed Activation	Problem associated with delayed or difficult activation of the **device**.	A150102
						Premature Activation	Problem associated with early and unexpected activation of the **device**.	A150103
						Self-Activation or Keying	Problem associated with the unintended activation of the **device**, or the **device** having been unexpectedly turned on during use.	A150104
			Positioning Problem	Problem associated with the movement of the **device** to an intended location.	A1502	Positioning Failure	Problem associated with the inability of the **device** to be positioned in a specified location.	A150201

						Malposition of device	Problem associated with the **device** being positioned in a location other than intended or specified.	A150202
						Difficult or Delayed Positioning	Problem associated with users experiencing difficulty or delay to position the **device** to a specified location.	A150203
						Failure to Advance	Problem associated with failure to move the **device** to an intended location.	A150204
						Difficult to Advance	Problem associated with difficulty moving the **device** to an intended location (e.g. difficulty in advancing guide wire).	A150205
						Difficult to Insert	Problem associated with problems introducing or inserting the **device**, even if the user is operating the **device** in accordance with the instructions for use or labeling.	A150206
						Difficult to Remove	Problem associated with the use of the **device** in terms of user experiencing difficulty to take out or get rid of the **device**, even if the user is operating device in accordance with the instructions for use or labeling.	A150207
						Entrapment of Device	Problem associated with the **device** caught within patient vasculature, tissue, or other **device**.	A150208
			Separation Problem	Problem associated with the detachment or separation of the **device**.	A1503	Separation Failure	Problem associated with the **device** or one of its components failing to detach or separate as intended.	A150301
						Difficult or Delayed Separation	Problem associated with users experiencing difficulty or delay with detachment or separation of the **device**.	A150302
						Premature Separation	Problem associated with an early and unexpected detachment or separation of the **device** from the system.	A150303
Protective Measures Problem	Problem associated with any deviations from the documented specifications of the **device** that relate to the implemented and inherited design features specific to devices used for reducing risks to patient or caregiver or maintaining risks within specified levels.	A16	Device Alarm System	Problem associated with the alarm system of the **device**.	A1601	Alarm Not Visible	The **device** does not display an alarm message when required.	A160101
						No Audible Alarm	The **device** fails to emit an audible alarm.	A160102
						Low Audible Alarm	The audible device alarm cannot be heard clearly.	A160103
						Delayed Alarm	The **device** alarm system operates with delay.	A160104
						False Alarm	Problem associated with the **device** providing incorrect alarm warning or alert to user.	A160105
						Defective Alarm	The **device** alarm does not operate as expected and/or in agreement with device's specifications.	A160106
			Fail-Safe Problem	Problem associated with the feature that prevents the unsafe use of the **device**.	A1602	Fail-Safe Did Not Operate	Problem associated with the **device** fail-safe mechanism, which did not function or function in a non effective way, compromising safe use of the device.	A160201
						No Fail-Safe Mechanism	The d**evice** does not have a fail-safe mechanism, although such mechanism would be required for its appropriate and/or safe functioning.	A160202
			Failure of Device to Self-Test	Problem associated with the **device** failing to perform an internal self-diagnostic process to ensure normal operation during or prior to use.	A1603			
			Failure to Auto Stop	Problem associated with the inability of device to turn itself off when the **device** is not in an operable condition.	A1604			

			Reset Problem	Problem associated with setting a variable, register, or other storage location back to a prescribed state.	A1605	Failure to Reset	Problem associated with the **device** failing to set a variable, register, or other storage location back to a prescribed state.	A160501
						Failure to Zero	Problem associated with the **device** failing to set a variable, register, or other storage location back to zero.	A160502
						Inappropriate or Unexpected Reset	Problem associated with the **device** setting a variable, register, or other storage location to an inappropriate or unexpected state.	A160503
			Premature Indicator Activation	Problems with the activation of a protective measure indicator earlier than expected.	A1606	Premature Elective Replacement Indicator	Problems with the early or unexpected activation of the elective replacement indicator.	A160601
						Premature End-of-Life Indicator	Problem with the early or unexpected activation of the end-of-life indicator.	A160602
			Shielding Failure	Problem associated with the **device** inability to act as a barrier for absorption of radiation energy in X-rays, gamma rays, etc.	A1607			
Compatibility Problem	Problem associated with compatibility between device, patients or substances (medication, body fluid, etc.)	A17	Component or Accessory Incompatibility	Problem associated with the incompatibility of any **device** while being operated in the same use environment thereby leading to a dysfunction between the **devices**.	A1701	Accessory Incompatible	An accessory required for the intended purpose of the **device** appears incompatible with device, thus compromising the intended function of the **device**.	A170101
						Component Incompatible	A component required for the proper functioning of the **device** is not compatible with other components or subassemblies of the **device**, thus compromising the intended function of the **device**.	A170102
			Device-Device Incompatibility	Problem associated with the incompatibility of two or more **devices** while being operated in the same use environment thereby leading to a dysfunction of more than one **device**.	A1702			
			Measurement System Incompatibility	Problem associated with the incompatibility of the measurement systems between and/or within **device** systems that are inherent to the individual **device** thereby leading to miscalculated or mismatched measurements from those **devices**, e.g., international metric system versus U.S. measurement system.	A1703			
			Unintended compatibility	Problem associated with the ability of two or more **devices** which are intended to be incompatible but are able to work or fit together.	A1704			
Contamination / decontamination Problem	Problem associated with the presence of any unexpected foreign substance found in the **device**, on its surface or in the package materials, which may affect performance or intended use of the **device**, or problem that compromise effective decontamination of the **device**.	A18	Contamination During Use	Problem associated with the undesired introduction of impurities either chemical or microbiological in nature, or of foreign matter into or onto the **device** at the user facility.	A1801	Biofilm coating in Device	Problem associated with the undesired introduction of a biofilm coating into or onto the **device**.	A180101
						Contamination of Device Ingredient or Reagent	Problem associated with the undesired introduction of impurities either chemical or microbiological in nature, or of foreign matter into or onto the **device** ingredient or reagent.	A180102
						Device Contamination with Body Fluid	Problem associated with the undesired presence of body fluid in/on the **device**, which are not part of the documented **device** specifications and requirements.	A180103
						Device Contamination with Chemical or Other Material	Problem associated with contamination of the **device** with chemical substance or other non biologic material.	A180104
						Microbial Contamination of Device	Problem associated with undesired microbial contamination of the **device**.	A180105

			Device Contaminated during manufacture or shipping	Problem associated with the presence of any unexpected foreign substance found on the surface or in the package materials, which may affect optimal performance for its intended use.	A1802			
			Device Reprocessing Problem	Problem associated with a failure during any step of reprocessing process (cleaning, disinfection, packaging, labeling, sterilization) of a used or opened from its original packaging, but unused, **device**.	A1803	Failure to Clean Adequately	Problem associated with the failure of the device or operator to remove any visible soil, foreign material or organism deposits on the external surfaces, crevices, and joints of the **device**.	A180301
						Failure to Disinfect	Failure to properly disinfect the **device** when reprocessing it.	A180302
						Flushing problem	Flushing process was not executed properly.	A180303
						Problem with Removal of Enzymatic Cleaner	Enzymatic cleaner was not removed properly.	A180304
						Problem with Sterilization	**Device** was not sterilized properly during reprocessing.	A180305
						Residue After Decontamination	Problem associated with the decontamination process not adequately removing unwanted visible soil, foreign material, or organism deposits.	A180306
Environmental Compatibility Problem	Problem associated with the surrounding conditions in which the **device** is being used such as temperature, noise, lighting, ventilation, or other external factors such as power supply.	A19	Ambient Noise Problem	Problem associated with any undesired acoustic energy or vibration that tends to interfere with the operation of the **device**.	A1901			
			Ambient Temperature Problem	Problem associated with compromised **device** performance at the ambient temperature or the storage at an inappropriate ambient temperature.	A1902			
			Fumes or Vapors	Problem associated with the visibility, odor, or toxicity of an ambient vapor or gas.	A1903			
			Fungus in Device Environment	Problem associated with the visibility of molds, mildews, yeasts, and/or mushrooms in the immediate environment in which the **device** is being used.	A1904			
			Moisture or Humidity Problem	Problem associated with an unsatisfactory humidity level in the storage or use environment which affects the **device** performance.	A1905	Moisture Damage	Problem associated with damage inflicted upon the **device** from water vapor or water in the immediate environment in which the **device** is being used.	A190501
			Ventilation Problem in Device Environment	Problem associated with the circulation of fresh air in the immediate atmosphere in which the **device** is being used.	A1906	Fogging	Problem associated with the visibility of water vapor in the immediate atmosphere in which the **device** is being used.	A190601
			Device Unsafe to Use in Environment	Problem associated with environmental condition that results in the unsafe use of the **device**. (e.g. electromagnetic fields, noise, vibration, microbiological contamination etc.)	A1907			
			Environmental Particulates	Problem associated with fine solids or liquid particles such as dust, smoke, fume, and/or mist suspended in the immediate atmosphere in which the **device** is being used.	A1908			
			Medical Gas Supply Problem	Problem associated with the facility-supplied medical gases such as medical air, oxygen, nitrous oxide, and nitrogen.	A1909			
			Electrical Power Problem	Problem associated with the quality of the facility-supplied power.	A1910	Emergency Power Failure	Problem associated with the failure of the facility's emergency power backup system(s) including generators and/or interruptible power systems (UPS).	A191001
						Loss of Power	Problem associated with the failure of primary power supplied by the facility.	A191002
						Power Conditioning Problem	Problem associated with a momentary overpower/over voltage from the utility and electrical systems of user facilities; - Problem associated with inadequate power conditioning such as the presence of fluctuation, surges, spikes, dropouts, noise and other such undesirable transients.	A191003

Installation-Related Problem	Problem associated with unsatisfactory installation, configuration, and/or setup of a specific **device**.	A20	Misassembled During Installation	Problem associated with the use of the **device** characterized by incorrect assembly of device components, parts or constituents.	A2001			
Labelling, Instructions for Use or Training Problem	Problem associated with **device** markings / labelling, instructions for use, training and maintenance documentation or guidelines.	A21	Device Markings / Labelling Problem	Problem associated with the written, printed or graphic material accompanying or affixed to the **device** or any of its packaging. This includes verbal instructions relating to identification, technical description, and usage provided by the **device** manufacturers. Problems can include but are not limited to this material being unclear, missing, worn out, incorrect or inaccurate.	A2101	Expiration Date Error	Problem associated with errors in identification of expiration date.	A210101
						Illegible Information	Problem associated with information unable to be read or deciphered.	A210102
						Inaccurate Information	Problem associated with imprecise, inexact information.	A210103
						Unclear Information	Problem associated with ambiguous, confused information.	A210104
						Missing Information	Absence of information e.g. labeling, instruction for use.	A210105
			Lack of Maintenance Documentation or Guidelines	Problem associated with user facility not receiving adequate service documentation, guidelines, or recommendations to perform preventative and corrective maintenance and performance assurance checks.	A2102			
			Inadequate Instructions for Healthcare Professional	Problem associated with inaccuracies in any written, printed, or graphic matter that is affixed to the **device** or its packaging with any matter that accompanies the **device** including verbal instructions related to identification, technical description and use of device provided by the **device** manufacturers that is intended for healthcare professionals.	A2103			
			Inadequate Instructions for Non-Healthcare Professional	Problem associated with users being unclear and not able to follow any written, printed, or graphic matter that is affixed to device or its packaging with any matter that accompanies the **device** including verbal instructions related to identification, technical description and use of the **device** provided by the **device** manufactures that vary from the standard of medical care in a given environment.	A2104			
			Inadequate or Insufficient Training	Problem associated with facility not providing satisfactory initial and/or periodic user training covering operation of the **device.**	A2105			
Human-Device Interface Problem	Problem associated with an act or omission of an act that has a different result than that intended by the manufacturer or expected by the operator.	A22	Device Difficult to Setup or Prepare	Problem associated with the use of the **device** in terms of user experiencing difficulty in preparing device for use, even if the operation is being performed according to labeled instructions for use.	A2201			
			Device Difficult to Program or Calibrate	The **device** is difficult to program, calibrate or set to desired state, even by appropriately trained user/operator.	A2202			
			Device Difficult to Maintain	Problem associated with the user's ability to service the **device** according to the manufacturer specifications relating to the **device** routine maintenance, i.e., periodic inspection, failure detection, repair, and care of the **device** to sustain or restore acceptable operating conditions.	A2203			
			Inadequate User Interface	Problem associated with the means by which the operator and the equipment communicate or interact.	A2204			

Use of Device Problem	Problem associated with failure to process, service, or operate the **device** according to the manufacturer's recommendations or recognized best practices.	A23	Device Handling Problem	Handling of the **device** not in accordance with specification, prior to use on the patient.	A2301			
			Use of Incorrect Control Settings	Problem associated with the use of the **device** in terms of inappropriate and false control setting for the **device**'s specified operation and/or intended use.	A2302			
			Improper or Incorrect Procedure or Method	Problem associated with the use of the **device** in terms of nonconforming to that device's intended use, specifications, procedure and process or service instructions and information provided by the **device** manufacturers.	A2303			
			Off-Label Use	Problem associated with the **device** which has been used for an unapproved indication or for an unapproved intended use.	A2304			
			Misassembled	Problem associated with incorrect assembly of the **device** or constituents after being put into use.	A2305	Misassembly by Users	Problem associated with incorrect assembly of the **device** or constituents by the users.	A230501
						Misassembly during Maintenance / Repair	Problem associated with incorrect assembly of the **device** or constituents during maintenance or repair.	A230502
Adverse Event Without Identified Device or Use Problem	An adverse event (e.g. patient harm) appears to have occurred, but there does not appear to have been a problem with the **device** or the way it was used.	A24						
No Apparent Adverse Event	A report has been received but the description provided does not appear to relate to an adverse event. This code allows a report to be recorded for administration purposes, even if it doesn't meet the requirements for adverse event reporting.	A25						
Insufficient Information	An adverse event appears to have occurred but there is not yet enough information available to classify the **device** problem.	A26						
Appropriate Term/Code Not Available	The **device** problem is not adequately described by any other term. Note: this code must not be used unless there is no other feasible code. The preferred term should be documented when submitting an adverse event report. This information will be used to determine if a new term should be added to the code table.	A27						

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Annex C Investigation Findings ("what were the findings?")

Device (bold): For the purpose of this Annex C, a **device** means a medical device including accessories and components.

Level 1			Level 2			Level3		
Term	Definition	Code	Term	Definition	Code	Term	Definition	Code
Biological Problem Identified	Problems relating to, caused by or affecting biological processes or living organisms.	C01	Biocompatibility Problem Identified	The **device** causes cellular or tissue responses that elicit an undesirable local or systemic effect in the recipient or beneficiary of that therapy. (See ISO 10993)	C0101			
			Biological Contamination	The undesirable presence of living organisms such as bacteria, fungi, or viruses or their products (enzymes or toxins).	C0102	Endotoxin Contamination	The undesirable presence of toxins associated with certain bacteria (e.g. gram negative bacteria).	C010201
						Microbial Contamination	The undesirable presence of microorganisms or microbes such as bacteria and fungi (yeasts and molds).	C010202
			Material or Material Leachate Pyrogenic Problem	The undesirable presence of pyrogens or fever-producing organisms caused by materials that permeate through the **device**.	C0103			
			Cytotoxicity Problem Identified	The **device** was found to have an undesirable level of toxicity to living cells.	C0104			
			Genotoxicity Problem Identified	The **device**'s ability to cause damage to genetic material (e.g. leading to malignant tumors). (See ISO 10993)	C0105	Carcinogenic Problem	The **device**'s ability to trigger development of cancer.	C010501
						Mutagenic Problem	The **device**'s ability to change genetic information (usually DNA) of an organism and thus increasing the frequency of mutations.	C010502

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				Hematological Problem Identified	The **device** affects or impacts the blood or its components. (See ISO 10993 all parts)	C0106	Agglutination Problem	The **device** affects the ability of the blood to clot which may be induced by chemical, mechanical, or thermal properties of the **device**.	C010601
							Complement Activation Problem	The **device** affects the body's ability to activate the complement system of the immune system, thereby interfering with the ability to clear pathogens. This may be caused by an interaction of the **device** with chemicals or materials.	C010602
							Platelet Activation Problem	The **device** affects the body's ability to activate platelet formation.	C010603
							Problem due to Thrombosis Activation	The **device** causes the formation of blood clots in or along blood vessels resulting in disturbed or disrupted blood flow.	C010604
				Unintended Presence of Allergens	Unintended or unexpected presence of allergens in the **device**. If the presence of the allergen is expected but not adequately labelled, then use "Labelling Problem".	C0107			
				Reproductive Toxicity Problem Identified	The **device** affects reproductive function, embryo development (teratogenicity), and prenatal and early postnatal development. (ISO 10993 part 3)	C0108			
Electrical Problem Identified	Events associated with an electrically powered **device** where an electrical malfunction results in a device problem (e.g. electrical circuitry, contact or component failed) even if the	C02	Electrical/Electronic Component Problem Identified	The performance of an electrical or electronic component was found to be inadequate.		C0201			

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		problem is intermittent.		Hardware Timing Problem Identified	Problems that results from improper sequential activation of components.	C0202		
				Impedance Problem Identified	Problems due to insufficient or excessive resistance to current flow either by the **device** or circuit.	C0203		
				Insulation Problem Identified	Problems due to inadequate or incorrect electrical insulation material.	C0204		
				Open Circuit	Problem due to an electrical circuit that does not conduct current because a switch is open, a wire is broken, etc.	C0205		
				Current Leakage Problem	Problems related to leakage currents which may cause electric shock. These currents usually flow through the protective ground conductor. In its absence, these currents could flow from the **device** to the ground via the human body.	C0206		
				Power Source Problem Identified	Problems related to the source that provides electrical power to the **device**.	C0207	Energy Storage System Problem	Problems related to the energy storage system (e.g. the rechargeable battery, charging system, or capacitor) and includes problems such as premature power source depletion and battery explosions.	C020701
							Loss of Power	A **device** that experienced problems due to a loss in the power supply.	C020702
							Power Fluctuation	The **device** failed due to fluctuations within the power supply (e.g. transient power, power spike, power dip, or power sequencing).	C020703

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			Short Circuit	Problems due to an unintentionally low-resistance connection between two points in an electric circuit, resulting in either excessive current flow that often causes damage or in a new shorter circuit that draws current away from the original pathways and components.	C0208			
			Signal Loss	Problems due to the loss or weakening of an electrical signal or signals.	C0209			
Electromagnetic Compatibility Problem Identified	**Device**-to-**device** or **device**-environment problem resulting from electromagnetic disturbances.	C03	Conducted Interference	Problems related to electromagnetic interference (EMI) by physical contact with conductors (e.g. wires, resistors, terminals) as opposed to radiated EMI which is caused by induction (without physical contact of the conductors).	C0301			
			Electrostatic Discharge	Problems due to sudden and momentary bursts of electrical current flowing between two objects at different electrical potentials.	C0302			
			Inadequate Immunity	Problems related to immunity or capabilities to resist electromagnetic interference (EMI).	C0303			
			Unintended Emission	Problems due to unintended emission of electromagnetic energy by the **device**.	C0304			
			Radiofrequency Interference (RFI)	Problems due to radiofrequency interference. RFI is a disturbance that affects an electrical circuit due to either electromagnetic conduction or electromagnetic radiation emitted from an external source.	C0305			

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Interoperability Problem Identified	Problems with the mechanical, electrical, or communication interface between two or more separate **devices**.	C04	Communications Problem Identified	**Devices** that do not send or receive adequate signals (this speaks to the interoperability between **devices**).	C0401	Wired Communication Problem	Communications problems between **devices** within a wired system.	C040101
						Wireless Communication Problem	Communications problems between **devices** within a wireless system.	C040102
						Network Communication Problem	Communications problems between **devices** within a network system.	C040103
			Incompatible Component/ Accessory	A **device** that malfunctions due to a component(s)/accessory that does not operate correctly and according to the **device**'s specifications.	C0402			
			Device Not Compatible With Another Device	A **device** that malfunctions due to being used in combination with, or in the presence of, another **device**.	C0403			
			Unintended Compatibility	The **device** was confirmed to be compatible with another **device** with which the **device** is intended to be incompatible.	C0404			
Labeling and Instructions for Use/Maintenance	Insufficient, inadequate, or incorrect information provided on a **device**'s label or documentation regarding e.g. its intended use, directions for use, and characteristics of the **device**, including its maintenance.	C05	Inadequate Labelling and/or Instructions for Use	Inadequate information on the labels or in the instructions for use e.g. steps that are difficult to follow or that are missing.	C0501			
			Incorrect Labeling and/or Instructions for Use	Missing, incorrect, or inappropriate information on the labels e.g. mislabeled contents or **device** labeling characteristics or package contents.	C0502			

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			Inadequate or Incorrect Instructions for Maintenance	Inadequate or incorrect information in the instructions for maintenance.	C0503			
Material and/or Chemical Problem Identified	Problems with the **device** materials or how its materials react to other elements either within the **device** or within the environment.	C06	Degradation Problem Identified	Problems that occur when the **device** becomes worn, weakened, corroded, or broken down due to processes such as aging, permeation, and corrosion.	C0601			
			Inappropriate Material	Problems that occur due to the presence of a material that should not be present or part of the **device**.	C0602	Improper Composition/ Concentration	Problems associated with the improper combination of materials or elements present in the **device** (e.g. improper composition of the materials of a capacitor).	C060201
						Improper Physical Structure	Problems related to the incorrect or inadequate arrangement of the parts, components, elements, or materials.	C060202
						Molecular Structure Problem	Problems related to the presence of an inappropriate molecular geometry somewhere in the **device** (i.e. the spatial arrangement of atoms in a molecule and the chemical bonds that hold the atoms together).	C060203
			Inadequate Physicochemical Properties	Problems that occur due to the physicochemical properties.	C0603			
			Incompatible Material	Problems that occur due to the incompatibility of materials that co-exist simultaneously as part of the **device**.	C0604			

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			Reactivity Problem Identified	Problems that occur due to the reactivity of materials (e.g. over-react or under-react).	C0605			
			Tolerance Stack-Up	Problems that result from a combination of specification variances of the components.	C0606			
Mechanical Problem Identified	Problems that result from internal or external forces including fluids, other objects, or environmental or physiologic influences.	C07	Device Migration	A **device** that has moved from its original location due to external forces (e.g. stent or lead movement).	C0701			
			Friction Problem Identified	Problems caused by its surface coming in contact with another surface or fluid.	C0702			
			Leakage/Seal	Problems caused by inadequate/broken seal within the **device**.	C0703			
			Lubrication Problem Identified	Problems that occurred because of the presence of either too much or too little lubricant where required (e.g. connectors, leading to failure mechanisms such as corrosion).	C0704			
			Stiffness Problem Identified	Problems that occurred when its material is either too flexible/pliable or inflexible/rigid when in contact by an applied force.	C0705			

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			Stress Problem Identified	Problems caused by either excessive or inadequate physical force exerted on it by another object resulting in problems e.g. wear, bending, deformation, fracture, fatigue.	C0706	Deformation Problem	Problems caused by changes in the shape or size of the **device** due to an applied force. This can be a result of tensile forces, compressive forces, shear, bending, tensile (pulling), or torsion.	C070601
						Fatigue Problem	Problems due to the weakening or breakdown of its material when subjected to stress or a series of repeated stresses.	C070602
						Fracture Problem	Problems caused by the separation of a component, object, or material into two or more pieces including shear.	C070603
						Mechanical Shock Problem	Problems caused by the sudden violent blow or collision to the whole **device** (e.g. by dropping).	C070604
						Vibration Problem	Problems caused by the constant rhythmic motion of the **device**, or something in the environment to which the **device** is exposed.	C070605
						Wear Problem	Problems due to the premature or expected erosion of its material by use, deterioration, or change.	C070606
			Incorrect Dimension	Problems caused by incorrect physical dimensions of the **device** or one of its parts	C0707			
Optical Problem Identified	Problems related to the optical properties of a **device**.	C08	Optical Transmission Problem Identified	Problems with the **device**'s ability to pass light energy.	C0801			

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			Light Source Problem Identified	Problems with the optical properties of a **device** such as diopter, glare, and irradiance or glistening.	C0802			
Clinical Imaging Problem Identified	Problems that occur with **devices** used for radiographic or imaging procedures e.g. CT scanners, magnetic resonance imaging.	C09	Gradient Induced Field Problem	Problems that result from the gradient-induced fields generated during radiologic procedures e.g. magnetic resonance imaging.	C0901			
			Image Artifact	The unacceptable distortion of an image due to signal loss that may occur during a radiologic procedure such as magnetic resonance imaging.	C0902			
			Magnetically-Induced Movement	Problems due to unintended or excessive movement created by the application of magnetic fields.	C0903			
			Radiofrequency Induced Overheating	Problems due to unintended radiofrequency-induced temperature increase that can occur in the vicinity of the **device**.	C0904			
Software Problem Identified	Problems related to the **device** software.	C10	Configuration Issue	Problems due to change control or incorrect version, including regional requirements.	C1001			
			Design Error	The **device** had faulty (incomplete or incorrect) software design.	C1002	Data Compression Error	Data was lost or corrupted during the operation of reducing storage space or communication bandwidth.	C100201
						Incorrect Algorithm	The **device** software was found to implement an incorrect sequence of steps for a specific computation.	C100202
						Incorrect Data Definition	The **device** software was found to contain errors in specifying or manipulating data items.	C100203

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						Interface Design Error	The **device** software was found to contain errors in the user interface (including usability problems) or the interfaces with other systems.	C100204
						Non-Functional Defect	The **device** software contained software errors that did not impact its operation.	C100205
						Software Timing Problem	Problems that results from the incorrect sequencing or activation of software modules.	C100206
			Software Maintenance Problem Identified	The **device** software was not maintained/updated properly.	C1003			
			Software Installation Problem Identified	The **device** software was not installed as per the specifications or failed to properly install.	C1004			
			Software Requirement Error	The software requirements for the **device** are either incomplete, inadequate, or in conflict.	C1005			
			Software Runtime Error	The **device** software failed during operation as a result of a coding error.	C1006			
			Software Security Vulnerability	The **device** software failed to provide adequate authorization, access control, protection and accountability features.	C1007			
			Erroneous Data Transfer	The **device** software fails to transfer the expected data within a system or to another **device**.	C1008			
			Data Storage or Loss of Data	Storage of data was unsuccessful in total or in part.	C1009			

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Thermal Problem	Problems related to the temperature of the **device**. Note: For problems related to environmental temperature use "Environment Problem Identified".	C11	Overheating Problem Identified	The **device** was found to become hotter than expected during operation. This applies to **devices** which are not intended to deliver heat. Use "Excessive heating identified" for **devices** which are intended to deliver heat during operation. Use "Inadequate cooling identified" if the overheating was related to a problem with a cooling system.	C1101			
			Excessive Heating Identified	The **device** delivered more heat than intended or expected during operation. This applies to **devices** which are intended to deliver heat. Use "Overheating problem identified" for **devices** which are not intended to deliver heat during operation.	C1102			
			Excessive Cooling Identified	The **device** cooled the patient or another **device** more than intended or expected during operation.	C1103			
			Inadequate Cooling Identified	The **device** did not sufficiently cool the patient or another **device** during operation.	C1104			
Protective System Problem Identified	Problems related to the system(s) designed to prevent or warn about unsafe operation of the **device**.	C12	Fail-safe Problem Identified	A system intended to prevent unsafe operation of the **device** did not operate correctly.	C1201			
			Alarm System Problem Identified	A system intended to warn of a potentially unsafe condition did not operate correctly.	C1202			
			Problem of Device to Self-Test	Malfunction of the **device**'s self-test system.	C1203			

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			Problem to Auto Stop	An auto stop function of a **device** did not operate correctly.	C1204			
			Premature Indicator Activation	A system intended to indicate the **device** status was triggered prematurely.	C1205			
			Reset Problem	The **device** does not reset properly.	C1206			
			Shielding Problem	Inadequate shielding of/by the **device**.	C1207			
			Missing or Inadequate Safety Measures	Safety measures are inadequately applied or missing.	C1208			
Operational Problem Identified	Problems that occur during the performance, use, or functioning of the **device**.	C13	Device Incorrectly Reprocessed	Problems associated with the failure to properly and adequately reprocess the **device**.	C1301	Device Incorrectly Cleaned During Reprocessing	The cleaning procedure is not followed correctly or used inappropriate cleaning materials.	C130101
						Device Incorrectly Disinfected/Sterilised During Reprocessing	The disinfection/sterilization process was incorrect and/or the wrong products for disinfection/sterilization were used.	C130102
						Device Incorrectly Assembled During Reprocessing	Incorrect assembly of the **device** following reprocessing.	C130103
			Failure to Calibrate	A **device** that cannot calibrate (establish the relationship between a measuring device and the units of measure) to ensure accurate readings.	C1302			
			Device Difficult to Operate	Problems including set-up, operation, and disassembly of equipment. Not including reprocessing.	C1303			

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			Incorrect Interpretation of Results/Data	Problems resulting from the incorrect interpretation by the user of the results or data provided by the **device**.	C1304			
Patient Sample Problem	Problems that occurred due to endogenous or exogenous interferent in the sample, or unexpected variation in the target analyte/marker.	C14	New or Unknown Interferent	New or unknown endogenous or exogenous interferent (sample) identified.	C1401			
			Known Interferent	Known interferent in the sample identified.	C1402			
			Change in Target Marker/Variant/ Mutant	Problem due to change in target marker/variant/mutant which is not covered in the labelling.	C1403			
			Pre-analytical Handling Problem	Incorrect pre-analytical handling of patient's sample by the user.	C1404			
Environment Problem Identified	Problems that occurred due to factors within the environment e.g. dust, dirt, humidity, temperature.	C15	Environmental Temperature Problem Identified	**Device** performance was affected by the temperature, or changes in temperature, of the environment in which it was used.	C1501			
			Dust or Dirt Problem Identified	A **device** that experienced problems due to ingress, or coating, of dust or dirt.	C1502			
			Contamination of Environment by Device	Operation of the **device** results in contamination of the nearby environment e.g. dust, dirt, smoke, heat or biological material.	C1503			
			Environmental Pressure Problem Identified	**Device** performance was affected by the pressure, or changes in pressure, of the environment in which it was used.	C1504			

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			Ambient Light Problem Identified	**Device** performance was affected by ambient light. This term applies to the direct effects of ambient light on the **device**, and to the user's ability to operate the **device** (e.g. to read **device** output).	C1505			
			Environmental Humidity Problem Identified	**Device** performance was affected by the humidity, or changes in humidity, of the environment in which it was used.	C1506			
Manufacturing Process Problem Identified	Problems with a **device** that can be traced to a problem in the manufacturing and/or production process.	C16	Assembly Problem Identified	Problems that occurred because the **device** was assembled incorrectly.	C1601			
			Sterilization Problem Identified	Problems that occurred during terminal sterilization by the manufacturer.	C1602			
			Installation Problem Identified	A **device** that malfunctions because it was incorrectly installed, set-up, or configured (e.g. misconfiguration of an "automatic" defibrillator to "semi-automatic", thereby leading to failure).	C1603			
			Maintenance of Manufacturing Machinery	Problems caused by failure to maintain manufacturing equipment used to produce the **device**.	C1604			
			Packaging Problem Identified	Problems that occurred because of the **device** packaging.	C1605	Packaging Compromised	Problems that occurred because of a compromised packaging of the **device** (e.g. broken or incomplete seal).	C160501
						Packaging Materials Problem	Problems that occurred because of the composition or type of packaging materials was inappropriate for the **device**.	C160502

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						Packaging Contains Unintended Material	Problems that occurred because unintended material was packaged with the **device**.	C160503
						Packaging Contains Incorrect Device	Problems that occurred because the packaging contained an incorrect **device**.	C160504
Maintenance Problem Identified	A **device** malfunction or problem that occurs after production because the **device** was not properly maintained according to the instructions (e.g. maintenance may be performed by user facility, distributor, or service provider).	C17						
Transport/Storage Problem Identified	Problems was caused by transport or storage conditions.	C18	Transport Problem Identified	Problems traced to how the **device** was transported e.g. temperature of shipping compartment or method of transportation.	C1801			
			Storage Problem Identified	Problems that result from storing the **device** in an uncontrolled or improper environment (e.g. moisture sensitive **devices** stored in a humid environment).	C1802			
No Device Problem Found	The **device** either functioned as intended or a problem was not found.	C19						
No Findings Available	Use when no investigation can be performed and therefore no results will be obtained.	C20						

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Results Pending Completion of Investigation	Investigation is ongoing and results are not yet available. Do not use this code if the investigation is complete.	C21						
Appropriate Term/Code Not Available	Problems is not adequately described by any other term. Note: This code must not be used unless there is no other feasible code. The preferred term should be documented when submitting an adverse event report. This information will be used to determine if a new term should be added to the code table.	C22						

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Annex D: Investigation Conclusion ("why did the incident/adverse event occur?")

Device (bold): For the purpose of this Annex D, a **device** means a medical device including accessories and components.

Level 1			Level 2		
Term	Definition	Code	Term	Definition	Code
Cause Traced to Device Design	Problems traced to the design specifications (e.g. in the requirements, testing processes, hazard analysis, implementation strategy).	D01	Design Inadequate for Purpose	Problems traced to design/design features of the **device** that do not support or interfere with the intended purpose of the **device**.	D0101
			Human Factors Engineering - Device Difficult to Operate	Problems traced to inappropriate and/or inadequate assessment and engineering design of the **device** to accommodate how or where the **device** will be used.	D0102
			Human Factors Engineering - Device Difficult to Assemble	Problems traced to inadequate design of the component parts and/or assembly steps resulting in the **device** not being able to be assembled correctly.	D0103
			Human Factors Engineering - Device Difficult to Reprocess	Problems traced to inadequate design of the reprocessing steps and/or the **device** resulting in the **device** remaining unclean.	D0104
			Missing or Inadequate Safety Measures	Problems traced to inadequate design or complete lack of safety measures leading to **device** malfunction or unintended properties of the **device** including possible hazards for persons using the **device**.	D0105
			Design Change Validation Inadequate	Problems traced to inadequate or lack of validation of design changes of the **device** leading to malfunction or unintended properties of the **device** including possible hazards for persons using the **device**.	D0106
Cause Traced to Component Failure	Expected or random component failure without any design or manufacturing issue.	D02			
Cause Traced to Manufacturing	A defect in the processes or systems used in the manufacture of the **device**. Examples include problems within the change control, production, or quality control processes.	D03	Manufacturing Deficiency	Problems traced to manufacturing process.	D0301
			Quality Control Deficiency	Problems traced to the failure to maintain or establish techniques for controlling and verifying the product specifications (including materials used) identified by the manufacturer himself.	D0302

Cause Traced to Transport/Storage	Problems traced to the inappropriate transport or storage of the **device**.	D04			
Cause Traced to Infrastructure	Problems traced to underlying framework, systems, and processes at the healthcare facility or other point of use (e.g. as building power supply, network, oxygen systems).	D05			
Cause Traced to Environment	Problems caused by exposure to environmental conditions outside the expected range.	D06			
Cause Traced to Maintenance	Problems traced to improper routine or preventative maintenance.	D07			
Cause Traced to Training	Problems caused by inadequate training.	D08			
Cause Traced to Labeling	Problems that occur as the result of problems with the labeling (including package inserts, instruction manuals, instructions for use).	D09			
Cause cannot be Traced to Device	The adverse event that occurred is not attributable to a **device**.	D10	Adverse Event Related to Patient Condition	An existing condition or disease is demonstrably responsible for the adverse event and use of the **device** has neither caused nor otherwise influenced this condition/disease-related adverse event.	D1001
			Adverse Event Related to Procedure	The adverse event occurred during the procedure and the **device** had no influence on event.	D1002
			Adverse Event Related to Commutability	The adverse event occurred because the material being used to calibrate or assess IVD performance did not have similar properties to those of human samples, leading to inappropriate bias and erroneous results. Examples of materials include: reference materials, calibrators, proficiency testing samples	D1003
Cause Traced to User	The adverse event caused partially or wholly by the user of the **device** including sample handling.	D11	Failure To Follow Instructions	Problems traced to the user not following the manufacturer's instructions.	D1101