**Reporting Form**

* Manufacturers can use their internal form as long as it covers all Data and Information below.
* N/A could be used if the information is not applicable.
* **ADMINISTRATIVE INFORMATION**
	+ Report Type (select one):
* Initial
* Follow-up
* Combined initial and final
* Final
	+ Classification of Event:
* Serious Public Health threat
* Death
* Serious Injury
* Minor injury
* Other Reportable Event
* Other, please specify:
	+ Date of this report (dd-mmm-yyyy):
	+ Date of incident/adverse event (dd-mmm-yyyy):
	+ AR awareness date (dd-mmm-yyyy):
	+ Manufacturer awareness date (dd-mmm-yyyy):
	+ Expected date of next report (dd-mmm-yyyy):
	+ Report Ref (assigned by manufacturer for the case):
	+ Information of the submitter of this report
		- Submitter of the report:
* Manufacturer
* Authorized representative
* Importer
* Distributor
* Other, please specify below:
	+ - * Name:
			* Establishment name:
			* Address:
			* Phone No:
			* E-mail:
* **EVENT INFORMATION:**
	+ Event Description:
	+ No. of affected people involved:
	+ No. of devices involved:
	+ Operator of device at the time of the event
* Healthcare Professional
* Patient
* Other, please specify:
* None
	+ Usage of Device
* Initial use
* Reuse of a reusable medical device
* Problem noted prior use
* Reuse of a single use medical device
* Re-serviced/refurbished/fully refurbished
* Other, please specify:
	+ Device Disposition / Current Location:
	+ Role of initial reporter:
* Healthcare professional
* Patient Lay user
* Other, please specify:
	+ **Medical device** problem codes:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Choice 1*(most relevant)* | Choice 2 | Choice 3 | Choice 4 | Choice 5 | Choice 6 |
| Medical device problem codes |  |  |  |  |  |  |

* **DEVICE/PRODUCT INFORMATION**
	+ Device Name:
	+ Authorization Number / Low Risk Device Number:
	+ Nomenclature System
	+ Medical device nomenclature code
	+ Catalogue/reference number
	+ Serial No.
	+ Lot/Batch No.
	+ Software version – if applicable –:
	+ Device manufacturing date (dd-mmm-yyyy)
	+ Device expiry date – if applicable – (dd-mmm-yyyy)
	+ Date when device was implanted – if applicable – (dd-mmm-yyyy)
	+ Date when device was explanted – if applicable – (dd-mmm-yyyy)
	+ If precise implant/explant dates are unknown, provide the duration of implantation:
	+ Risk class of device – if applicable –:
	+ Manufacturer Information:
		- Name:
		- Contact Person:
		- Address:
		- Phone:
		- E-mail:
* **RESULT OF MANUAFCTURER’S INVESTIGATION**
	+ Manufacturer’s preliminary comments:
	+ For **initial** and **follow-up** reports: preliminary results and conclusions of manufacturer’s investigation:



* + Initial actions (corrective and/or preventive) implemented by the manufacturer:
	+ Cause investigation and conclusion
	+ For Final (Reportable incident): Description of the manufacturer’s evaluation concerning possible root causes/causative factors and conclusion
	+ Is root cause confirmed?
		1. Yes
		2. No
	+ Has the risk assessment been reviewed?
		1. Yes
		2. No
	+ If the risk assessment has been reviewed, is it still adequate?
		1. Yes
		2. No
	+ **Cause Investigation** terms and codes:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Choice 1*(most relevant)* | Choice 2 | Choice 3 | Choice 4 | Choice 5 | Choice 6 | Choice 7 | Choice 8 |
| Causeinvestigation: Type of investigation(Annex B) |  |  |  |  |  |  |  |  |
| Causeinvestigation:Investigation findings(Annex C) |  |  |  |  |  |  |  |  |
| Causeinvestigation:Investigationconclusion (Annex D) |  |  |  |  |  |  |  |  |

* + **Health Effect** terms and codes

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Choice 1*(most relevant)* | Choice 2 | Choice 3 | Choice 4 | Choice 5 | Choice 6 | Choice 7 | Choice 8 |
| Clinical signs,symptoms, and conditionscodes' (Annex E) |  |  |  |  |  |  |  |  |
| 'Health impact'codes (Annex F) |  |  |  |  |  |  |  |  |

* **INFORMATION OF PATIENT**
1. Age at time of event (months, years):
2. Gender (M/F):
3. Weight (kg):
4. List of devices involved with the patient (see Section IV):
5. Corrective action taken relevant to the care of the patient:
6. Patient outcome:
* **HEALTHCARE FACILITY INFORMATION**
	+ Name of the Facility:
	+ Name of Contact Person:
	+ Address:
	+ Phone:
	+ E-mail:
* **COMMENTS**