**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 |
| Cause  investigation: Type of investigation  (Annex B) |  |  |  |  |  |  |  |  |
| Cause  investigation:  Investigation findings  (Annex C) |  |  |  |  |  |  |  |  |
| Cause  investigation:  Investigation  conclusion (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 conditions  codes' (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**