**Reporting Template**

**Sector:** Medical Devices

**Executive Department**: Surveillance and Biometrics

**Department:** Surveillance

**Section:** Investigation

**Code:** MDS-F-310-024-V2

**Related SOP:** Policy and Procedure of Adverse event, Incident and Complaint Investigation

**Approval Date:** 28/11/2023

**Version Control**

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision Date** | **Version NO.** | **Reason of change** | **Describe the change** |
| 08/04/2021 | V1 | New | - |
| 2023/11/28 | V2 | Update | Added Submitter Name Title. |

**Issued By:** Eng. Ahmed Al-Qarni

**Position:** Surveillance Expert

* Manufacturers can use their internal form as long as it cover all Data and Information
* N/A could be used if the information is not applicable.

1. **ADMINISTRATIVE INFORMATION**

* Report Type (select one):

Initial

Follow-up

Combined initial and final

Final

* Classification of Event:

Serious Public Health Concern

Death

Serious Injury

Minor injury

Other Reportable Event

Other: Click or tap here to enter text.

* Date of this report: Click or tap to enter a date.
* Date of incident/adverse event: Click or tap to enter a date.
* AR awareness date: Click or tap to enter a date.
* Manufacturer awareness date: Click or tap to enter a date.
* Expected date of next report: Click or tap to enter a date.
* Report Ref (assigned by manufacturer for the case): Click or tap here to enter text.

**Information of the submitter of this report:**

* Submitter of the report:

Manufacturer

Authorized representative

Importer

Distributor

Other, please specify: Click or tap here to enter text.

* Name: Click or tap here to enter text.
* Establishment name: Click or tap here to enter text.
* Address : Click or tap here to enter text.
* Mobile Phone No: Click or tap here to enter text.
* E-mail: Click or tap here to enter text.

1. **EVENT INFORMATION:**

* Event Description:

Click or tap here to enter text.

* No. of affected people involved: Click or tap here to enter text.
* No. of devices involved: Click or tap here to enter text.
* IMDRF Medical device problem codes (Annex A)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Choice 1  *(most relevant)* | Choice 2 | Choice 3 | Choice 4 | Choice 5 | Choice 6 |
| IMDRF 'Medical device problem codes' | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. |

1. **HEALTHCARE FACILITY INFORMATION**

* Name of the Facility: Click or tap here to enter text.
* Name of Contact Person: Click or tap here to enter text.
* Address : Click or tap here to enter text.
* Phone: Click or tap here to enter text.
* E-mail:Click or tap here to enter text.

1. **DEVICE/PRODUCT INFORMATION**

* Device Name: Click or tap here to enter text.
* Product Registration No.: Click or tap here to enter text.
* Nomenclature System: Click or tap here to enter text.
* Medical device nomenclature code: Click or tap here to enter text.
* Catalogue/reference number: Click or tap here to enter text.
* Serial No.: Click or tap here to enter text.
* Lot / Batch No.: Click or tap here to enter text.
* Software version: Click or tap here to enter text.
* Device manufacturing Click or tap to enter a date.
* Device expiry date Click or tap to enter a date.
* Date when device was implanted Click or tap to enter a date.
* Date when device was explanted Click or tap to enter a date.
* If precise implant/explant dates are unknown, provide the duration of implantation: Click or tap here to enter text.
* Risk class of device: Click or tap here to enter text.
* Legal Manufacturer Information:
* Name: Click or tap here to enter text.
* Contact Person: Click or tap here to enter text.
* Address: Click or tap here to enter text.
* Phone: Click or tap here to enter text.
* E-mail: Click or tap here to enter text.
* Operator of device at the time of the event

Healthcare Professional

Patient

Other

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: Click or tap here to enter text.

1. **RESULT OF MANUAFCTURER’S INVESTIGATION**

* Manufacturer’s preliminary comments:
  + For **initial** and **follow-up** reports: preliminary results and conclusions of manufacturer’s investigation:

Click or tap here to enter text.

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

Click or tap here to enter text.

* Cause investigation and conclusion
  + For Final (Reportable incident): Description of the manufacturer’s evaluation concerning possible root causes/causative factors and conclusion

Click or tap here to enter text.

* IMDRF ‘Cause Investigation' terms and codes (Annex B, C, D)

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Choice 1  *(most relevant)* | Choice 2 | Choice 3 | Choice 4 | Choice 5 | Choice 6 | Choice 7 | Choice 8 |
| IMDRF Cause  investigation: Type of investigation  (Annex B) | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. |
| IMDRF Cause  investigation:  Investigation findings  (Annex C) | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. |  |  |
| IMDRF Cause  investigation:  Investigation  conclusion (Annex D) | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. |  |  |

1. **INFORMATION OF PATIENT**

* IMDRF 'Health Effect' terms and codes (Annex E, F)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Choice 1  *(most relevant)* | Choice 2 | Choice 3 | Choice 4 | Choice 5 | Choice 6 |
| IMDRF 'Clinical signs,  symptoms, and conditions  codes' (Annex E) | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. |
| IMDRF 'Health impact'  codes (Annex F) | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. | Code  Click or tap here to enter text. |

* Age at time of event (months, years): Click or tap here to enter text.
* Gender (M/F): Click or tap here to enter text.
* Weight (kg): Click or tap here to enter text.
* List of devices involved with the patient (see Section IV): Click or tap here to enter text.
* Corrective action taken relevant to the care of the patient: Click or tap here to enter text.
* Patient outcome: Click or tap here to enter text.

1. **OTHER REPORTING INFORMATION**

* Role of initial reporter:

Healthcare professional

Patient Lay user

Other, please specify: Click or tap here to enter text.

* Name of healthcare facility where incident occurred: Click or tap here to enter text.
* Contact Information: Click or tap here to enter text.

1. **COMMENTS**

Click or tap here to enter text.

**Submitter Name**: Click or tap here to enter text.

**Submitter** **Title**: Click or tap here to enter text.