Appendix No.2: Medical Device Reporting Form for Manufacturers, marketing authorization holder, importers, authorized agents/ representatives, distributors, suppliers and registrants or any other person who is responsible for placing the device on the market

Is there a patient involvement? □ Yes □ No

1. ADMINISTRATIVE INFORMATION

- Report Type (select one):
  - Initial
  - Follow-up
  - Combined initial and final
  - Final

- Date of this report (dd-mmm-yyyy)
- Date of incident/adverse event (dd-mmm-yyyy)
- Responsible person awareness date (dd-mmm-yyyy)
- Manufacturer awareness date (dd-mmm-yyyy)
- Expected date of next report (dd-mmm-yyyy)
- Report Reference Number (assigned by manufacturer for the case):

Information of the submitter of this report:

- Submitter of the report:
  - Manufacturer
  - Authorized agent / representative
  - Importer
  - Distributor
  - Other, please specify
- Name:
- Address:
- Mobile Phone No:
- E-mail:

Information of the initial reporter:

- Role of initial reporter:
  - Healthcare professional
  - Patient Lay user
  - Other, please specify

- Name of healthcare facility where incident occurred:
- Contact Information:

2. EVENT INFORMATION

- Event Description:

- No. of affected people involved:
- No. of devices involved:

- Does the incident represent a serious public health threat? □ Yes □ No

- Consequences of Product problem(s): Serious: □ Yes □ No

- If Serious Please indicate the reason of seriousness:
  - Patient Died
  - Life threatening
  - Hospitalization
  - Prolonged Hospitalization
  - Congenital Anomaly/Birth Defects
  - Disability or Permanent Damage
  - Required Intervention to Prevent Permanent Impairment/Damage
  - Other, specify

- Manufacturer/Sponsor aware of other similar events? (number or rate)

- 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	Code	Code	Code	Code	Code

3. HEALTHCARE FACILITY INFORMATION

- Name of the Facility:
- Name of Contact Person:
- Address:
- Phone:
- E-mail:

4. DEVICE/PRODUCT INFORMATION

- Brand Name:
- Commercial Device Name:
- Manufacturer Name:
- Product Registration No.
- Model / Catalogue number
- Serial No.
- Lot / Batch No.
- Unique Identifier (UDI) No.
- Software version No. (if applicable)
- Device manufacturing date (dd-mmm-yyyy)
- Device expiry date (dd-mmm-yyyy)

- Type of Device (mark one only):

□ Active implantable devices
□ Administration& giving sets
□ Anesthetic machines& monitors
□ Anesthetic & breathing masks
□ Autoclaves
□ Bath aids
□ Beds& mattresses
□ Blood pressure measurement
□ Breast implant
□ Cardiovascular implants& devices
□ Commodes
□ Contact Lenses& care Products
□ CT systems
□ Dental materials& applications
□ Dialysis equipment
□ Diathermy equipment& accessories
□ Dressings
□ Endoscopes& accessories
□ Endotracheal tubes& airways
□ Ophthalmic equipment
□ External defibrillators& pacemakers
□ Feeding tubes
□ Gloves
□ Guide wires
□ Hearing aids
□ Hypodermic Syringes& needles
□ Implant materials
□ Infant incubators
□ Infusion pumps, syringe drivers
□ Insulin syringes
□ Intravenous catheters& cannula
□ IVD (In Vitro Diagnostic) device
□ Joint prostheses
□ Lasers& accessories
□ Magnetic resonance equipment& accessories
□ Mobile x-ray systems
□ Monitor& electrodes
□ Non-active implants
□ Patient hoists
□ Physiotherapy equipment
□ Radiotherapy equipment
□ Radionuclide equipment
□ Resuscitators
□ Stapler& staples
□ Stretchers
□ Surgical instruments
□ Surgical powder
□ Sutures
□ Thermometers
□ Ultrasound equipment
□ Urinary catheters
□ Ventilators
□ Walking Sticks/ Frames
□ Wound drains
□ X-ray equipment systems& accessories
□ Others (Please specify):

For implants only:

- Implant date (dd/mm/yyyy):
- Explant date (dd/mm/yyyy):
- Duration of implantation (to be filled if the exact implant and explant dates are unknown)

- Device Available for Evaluation?
  - Yes
  - No
  - Returned to Manufacturer on (dd-mmm-yyyy):

- Usage of Medical Device:
  - Initial use
  - Reuse of single use medical device
  - Reuse of reusable medical device
  - Re-serviced/Refurbished
  - Problem noted prior to use
  - Others, Specify

- Operator of medical device at the time of the event (select one)
  - Health Professional
  - Patient
  - Others

- Device Disposition / Current Location:

5 . 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:

- 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	Code	Code	Code	Code	Code	Code	Code
IMDRF Cause investigation: Investigation findings (Annex C)	Code	Code	Code	Code	Code	Code		
IMDRF Cause investigation: Investigation conclusion (Annex D)	Code	Code	Code	Code	Code	Code		

5. 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	Code	Code	Code	Code	Code
IMDRF 'Health impact' codes (Annex F)	Code	Code	Code	Code	Code	Code

- Age at time of event (months, years):
- Gender (M/F):
- Weight (kg):
- Corrective action taken relevant to the care of the patient:
- Patient outcome:

6. **COMMENTS**

*Fields in red are mandatory.

The Required Data and Information for Reporting MD with No patient involvement

- Report Type
- Reporter Name
- Reporter email
- Reporter mobile
- Date of Submission (m/d/y)
- Date of incident (m/d/y)
- Manufacturer awareness date (m/d/y)
- Device/Product Name
- Manufacturer Name
- Model
- Serial Number
- Lot number
- Incident/problem Description
- Health impact
- Result