# MEDICAL DEVICE ADVERSE EVENT REPORTING FORM

## Materiovigilance Programme of India (MvPI)

**This form is intended to collect information on Medical Devices Adverse Event in India. The form is designed to be used voluntarily by Manufacturer/Importer/Distributor of Medical Devices, Healthcare Professionals and anyone with direct/indirect knowledge of Medical Devices Adverse Event.**

## General Information

1. Date of Report :
2. Type of Report : Initial ☐ Follow up ☐ Final ☐ Trend ☐
3. Reporter Reference for MDMC only: • Centre • Location • Month-Year • Case No.

## Reporter Details

1. Type of Reporter : (a) Manufacturer ☐ (b) Importer ☐ (c) Distributor ☐ (d) Healthcare Professional ☐
   (e) Patient ☐ (f) Others ☐ specify .....
2. In case, where the reporter is not manufacturer, fill the following details:-
   (a) Has the reporter informed the incident to the manufacturer?
   Yes ☐ No ☐
   (b) Is the reporter also submitting the report on behalf of the manufacturer?
   Yes ☐ No ☐
3. Reporter contact information:
   a) Name :
   b) Address :
   c) Tel. /Mobile :
   d) Email :

## Device Category

| Medical Device | In Vitro Diagnostics (IVD) | Medical Equipments / Machines |
|---|---|---|
| I. Therapeutic ☐ Diagnostic ☐ | I. Kits ☐ | I. Therapeutic ☐ Diagnostic ☐ |
| Both ☐ Preventive ☐ | II. Reagents ☐ | II. Therapeutic & Diagnostic ☐ |
| Assistive ☐ | III. Calibrator ☐ | III. Preventive ☐ |
| II. Implantable device ☐ | IV. Control Material ☐ | IV. Assistive ☐ |
| Non-Implantable device ☐ | V. Others ☐ | V. Imaging ☐ |
| III. Invasive ☐ Non-Invasive ☐ | VI. IVD electronic reader/ ☐ | VI. Invasive ☐ Non-Invasive ☐ |
| IV. Single use device ☐ | Analyzer | VII. Others ☐ |
| Reusable device ☐ | | |
| Reuse of manufacture marked Single use device ☐ | | |
| V. Sterile ☐ Non Sterile ☐ | | |
| VI. Personal use / Homecare use ☐ | | |

**Instruction for use Section A-F**

- ***If Medical Devices/Equipments/Machines : Please fill all the sections i.e. A, B, C, D, E & F***
- ***If in Vitro Diagnostics (IVD) : Please fill sections i.e. A (except 6, 7, 8, 13, 14 & 16), B (except 1, 2, 6 & 8), D, E, & F***

## (A) Device Details

**Device Name / Trade Name / Brand Name: ……**

| Details | Name | Address |
|---|---|---|
| **Manufacturer** | | |
| **Importer** | | |
| **Distributor** | | |

1. a) Is the device notified/regulated in India : Yes ☐ No ☐

   b) Device Risk Classification as per India MDR 2017 : A ☐ B ☐ C ☐ D ☐
2. License No. (Manufacture/Import) :
3. Catalogue No. :
4. Model No. :
5. Lot / Batch No. :
6. Serial No. :
7. Software Version :
8. Associated Devices / Accessories :
9. Nomenclature Code if applicable; GMDN/UMDNS :
10. UDI No. (If applicable) :
11. Installation Date :
12. Expiration Date :
13. Last preventive maintenance date (dd/mm/yyyy) :
14. Last calibration date (dd/mm/yyyy) :
15. Year of manufacturing :
16. How long was device/Equipment/Machine in use :
17. Availability of device for evaluation : Yes ☐ No ☐

    If no, was the device destroyed ☐ Still in use ☐ return to manufacturer or importer/distributor ☐
18. Is the usage of device as per manufacturer claim /Instruction for use/user manual: Yes ☐ No ☐

    If no specify usage ……

    ……
19. For devices not regulated / notified in India : Regulator / Regulatory status in country of origin

    ……

## (B) Event Description

1. Date of Event / Near miss incident:
2. Date of Implant/Explant (If applicable):
3. Location of Event:

   Hospital Premise ☐ Manufacture/Distributor premise ☐

   Home ☐ Others ☐
4. Device Operator:-

   Healthcare Professional ☐ Patient ☐ Others ☐

   Problem noted prior to use/near miss event ☐
5. Device disposition / Current location:

   a) Returned to company ☐ If yes, date ……/……. /……

   b) Remains implanted in patient ☐

   c) Within the healthcare facility ☐

   d) At patient home ☐

   e) Destroyed ☐

   f) Others (specify) ☐
6. Is device in use after incidence : Yes ☐ No ☐
7. Serious event: ☐

   If serious, Tick the appropriate reason

   a) Death (DD/MM/YY) ☐ ……/……/……

   b) Life Threatening ☐

   c) Disability or permanent damage ☐

   d) Hospitalization ☐

   e) Congenital anomaly /birth defect ☐

   f) Any other serious (Imp. medical event) ☐

   g) Required intervention to prevent / permanent Impairment / damage device ☐
8. Non serious event ☐
9. Whether other medical devices were used at same time with above device if yes, please specify name(s)/use(s)

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   ……

**10. Detail description of Event:-**

***For manufacturer/authorized representative use only***

| 11. Frequency of occurrence of similar Adverse Event in India in past 3 years | Year | No. of Similar Adverse Events | Total No. Supplied | Frequency of Occurrence (%) |
|---|---|---|---|---|
| | | | | |
| 12. Frequency of occurrence of similar Adverse Event in globally in past 3 years | Year | No. of Similar Adverse Events | Total No. Supplied | Frequency of Occurrence (%) |
| | | | | |

## (C) Patient Information, History & Outcome

1. Patient Hospital ID :
2. Patient Initial :
3. Age :
4. Gender : Male ☐ Female ☐ Others ☐
5. Weight :
6. Other relevant history, including pre-existing medical conditions……

   ……

   ……

   ……

   ……
7. Patient Outcomes:

   a) Recovered Date (DD/MM/YY) ☐ ……/……/……

   b) Not yet recovered ☐

   c) Death ☐ (DD/MM/YY) ☐ ……/……/……

   d) Others ☐

   Please specify……

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   ……

   ……

## (D) Healthcare Facility Information (if available)

1. Name :
2. Address :
3. Contact Person Name at the site of event :
4. Tel. No. :

## (E) Causality Assessment

1. Investigation action taken:

2. Root cause of problem (Applicable for follow up / final reports):

## (F) Manufacturer/Authorized Representative Investigation & Action taken

1. Manufacturer/Authorized Representative device risk analysis report:

2. Corrective / preventive action taken:

3. Device history review:

**Where to report?**

**Duly filled Medical Device Adverse Event Reporting Form can be sent to Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India, Sector-23, Rajnagar, Ghaziabad-20002, Tel-0120-2783400, 2783401 and 2783392, FAX:0120-2783311 or email to mvpi.ipcindia@gmail.com Or Call on Helpline no. 1800 180 3024 to report Adverse event.**

**Partnering Organizations**

**Disclaimer**

**Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the adverse event.**