|  |  |  |
| --- | --- | --- |
|  | **Medical Device Adverse Event Reporting Form**  **for Medical Device Dealers** |  |
| This form may take you 15 minutes to fill in.  You will need to prepare some information to fill in the form.  **EXPLANATORY NOTES**  **Who should report using this form?**  This form is intended for manufacturers, importers, suppliers or registrants of medical device for mandatory reporting of adverse events that they become aware of in relation to medical devices they deal with. Under the Health Products Act and Health Products (Medical Devices) Regulations 2010, reporting of adverse events is a duty that has to be performed by manufacturers, importers, suppliers or registrants of medical devices.  **What needs to be reported?**  For information on reportable adverse events and the reporting timelines, please refer to GN-05: Guidance on the Reporting of Adverse Events for Medical Devicesfor more information.  Submission of a report does not constitute an admission that medical personnel or the health product caused or contributed to the incident.  **How to Submit the Report Form?**  This form, once completed, and any attachment should be submitted via email to hsa\_medical\_device@hsa.gov.sg. Submission of this form via email would constitute a submission under Section 42 of the Health Products Act. Submission of false or misleading information is an offence.  The Authority reserves its right to reject submissions that are not in the prescribed form or manner. | | | |

|  |  |
| --- | --- |
| **MANDATORY MEDICAL DEVICE ADVERSE EVENT REPORTING FORM**  *Fields marked with an asterisk \* are mandatory fields to be completed before submission* | |
| I – GENERAL INFORMATION | |
| HSA Adverse Event Reference No. |  |
| Product Owner Reference No. |  |
| Report Type \* | Initial  Follow-up  Final  Trend |
| AE Category \* | Serious Public Health Threat  Death  Serious Deterioration in State of Health  Others |
| Date of Adverse Event *(dd/mm/yyyy)* \* | Click here to enter a date. |
| Date Company aware *(dd/mm/yyyy)* | Click here to enter a date. |
| II – PARTICULARS OF REPORTING COMPANY | |
| Name of company \* |  |
| Company address |  |
| Contact person name \* |  |
| Designation |  |
| Tel no. |  |
| Email Address \* |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| III – DEVICE DETAILS | | | | | |
| Device Name \* |  | | | | |
| Usage of Device/Intended Purpose |  | | | | |
| Device Regulatory Status (e.g. SMDR Listing No. if device is registered) |  | | | | |
| Catalogue No. \* |  | | | | |
| Model No. \* |  | | | | |
| Lot/Batch No. |  | | | | |
| Serial No. |  | | | | |
| UDI – Device Identifier (UDI-DI) |  | | | | |
| Direct Marking Device Identifier (DM-DI) |  | | | | |
| Software version |  | | | | |
| Accessories/Associated Devices affected (if any) |  | | | | |
| GMDN Code |  | | | | |
| GMDN Term |  | | | | |
| Product Owner Name |  | | | | |
| Product Owner Address |  | | | | |
| IV – DESCRIPTION OF EVENT | | | | | |
| Device Operator | Physician  Patient  Others (Please specify:      )  None or problem noted prior to use | | | | |
| Device disposition/current location |  | | | | |
| Description of Event or Problem (including any patient follow up as a result of the event/problem) \* |  | | | | |
| Frequency of Occurrence of Similar Adverse Events Globally in the past 3 years (Number of adverse events/Total number supplied by year) | Year | No of similar AEs | | Total number supplied | Frequency of occurrence (%) |
|  |  | |  |  |
|  |  | |  |  |
|  |  | |  |  |
| Frequency of Occurrence of Similar Adverse Events in Singapore in the past 3 years (Number of adverse events/Total number supplied by year) | Year | No of similar AEs | | Total number supplied | Frequency of occurrence (%) |
|  |  | |  |  |
|  |  | |  |  |
|  |  | |  |  |
| No. of Patients Involved in this AE |  | | | | |
| No. of Devices Involved in this AE |  | | | | |
| Was the device implanted? | Yes  No  Implantation Date: Click here to enter a date. | | | | |
| V – RESULTS OF PRODUCT OWNER’S INVESTIGATION | | | | | |
| Product Owner’s Device Analysis results |  | | | | |
| Device History Review |  | | | | |
| Course of Action/ Remedial/ Corrective/ Preventive action |  | | | | |
| VI – International Medical Device Regulators Forum (IMDRF) Adverse Event Terminology (Codes and Terms can be obtained from: [*https://www.imdrf.org/working-groups/adverse-event-terminology*](https://www.imdrf.org/working-groups/adverse-event-terminology)) | | | | | |
| [Annex A - Device Problem](https://www.imdrf.org/working-groups/adverse-event-terminology/annex-medical-device-problem) | | | *e.g. A010101 - Biocompatibility* | | |
| [Annex B - Cause Investigation - Type of Investigation](https://www.imdrf.org/working-groups/adverse-event-terminology/annex-b-cause-investigation-type-investigation) | | |  | | |
| [Annex C - Cause Investigation - Investigation Findings](https://www.imdrf.org/working-groups/adverse-event-terminology/annex-c-cause-investigation-investigation-findings) | | |  | | |
| [Annex D - Cause Investigation – Investigation Conclusion](https://www.imdrf.org/working-groups/adverse-event-terminology/annex-d-cause-investigation-investigation-conclusion) | | |  | | |
| [Annex E - Health Effects - Clinical Signs and Symptoms or Conditions](https://www.imdrf.org/working-groups/adverse-event-terminology/annex-e-health-effects-clinical-signs-and-symptoms-or-conditions) | | |  | | |
| [Annex F - Health Effects - Health Impact](https://www.imdrf.org/working-groups/adverse-event-terminology/annex-f-health-effects-health-impact) | | |  | | |
| [Annex G - Medical Device Component](https://www.imdrf.org/working-groups/adverse-event-terminology/annex-g-medical-device-component) | | |  | | |
| VII – PATIENT INFORMATION (Please do not include patient name or any other patient identifiable information in this section) | | | | | |
| Age of patient at time of event *(years)*\* |  | | | | |
| Sex \* | Choose an item. | | | | |
| Patient Outcome | Recovered (Date *(dd/mm/yyyy)*: Click here to enter a date.)  Not yet recovered  Death (Date *(dd/mm/yyyy)*: Click here to enter a date.)  Others (Please specify:      ) | | | | |
| VII – HEALTHCARE FACILITY INFORMATION | | | | | |
| Name (*Healthcare Institution*) \* |  | | | | |
| Address |  | | | | |
| Contact Name at site of event |  | | | | |
| Job title |  | | | | |
| Tel no. |  | | | | |
| Email Address |  | | | | |
| VIII – OTHER INFORMATION | | | | | |
|  | | | | | |

I attest that the information submitted is true and accurate, and that I am authorized to submit this form on behalf of the company.

**Guidance on how to fill this form**

The following provides some guidance on what information is required in some parts of the form.

**General Information**

Each field must be completed with the requested information, “NA” if not applicable, or “unknown” when the data is not available. If the space provided in the form is insufficient, please provide the information as an attachment. You may also use the “Other Information” section at the end of the form to provide any additional details that are relevant and not requested elsewhere.

Reference Number

* *HSA Adverse Event Reference No.:* The reference number given by Medical Devices Branch (MDB) during acknowledgement of the adverse event. It is used as a reference for future correspondence with MDB. This reference no. would only become available after the initial report has been submitted.
* *Product Owner Reference No.:* The reference number assigned by the product owner for the medical device.

###### Report type

* *Initial*: The first report that the reporter (dealers and registrant) is submitting about an event. The reporter is expected to submit further information about the event within 30 days.
* *Follow-up*: Additional information to a previous (initial or follow-up) report.
* *Final*: The last report that the reporter expects to submit about an event. The initial report can be a final report if the reporter has all the information about the event.
* *Trend*: Significant changes in frequency of occurrence or severity of events associated with devices must be reported. These reports are called trend reports. Under the quality management system requirements, the manufacturer is expected to monitor trends of significant adverse events.

###### Report Category

* *Serious Threat to Public Health*: Select this category when the event represents a serious threat to public. The initial report for this category of adverse events must be submitted not later than 48 hours after the reporter becomes aware of the event.
* *Death/Serious Deterioration in State of Health*: Select this category when the adverse event results in the death or serious deterioration in state of health of a patient, user or other person. The initial report for this category must be submitted not later than 10 days after the reporter becomes aware of the event.
* *Others*: Select this category when the adverse event was a near incident or is the result of testing or other analysis and event or further occurrence could lead to death or serious injury or a patient, user or other person. The initial report for this category must be submitted not later than 30 days after the reporter becoming aware of the event.

###### Device Information

* *Device Regulatory Status:* Indicate the regulatory approval numbers that apply to all devices affected by the AE, i.e. SMDR Listing No., Special Authorisation Route Licence No. If device has been exempted from product registration, indicate the basis for exemption, e.g. class A non-sterile MD.
* *SMDR Listing No*.: The number assigned to the device in the Singapore Medical Device Register, in the format of DEXXXXXXX. ‘X’ referring to the numeric number assigned to the device listing.
* *GMDN Code and Term*: Global Medical Device Nomenclature Code and explanatory term, e.g. 13906 – Suture, polyester.
* *UDI – Device Identifier (UDI-DI): The UDI-DI is a unique numeric or alphanumeric code specific to a model of medical device and that is also used as the "access key" to information stored in a UDID. Examples of the UDI-DI include GS1 GTIN (Global Trade Item Number), HIBC-LIC (Labeler Identification Code), ISBT 128-PPIC (Processor Product Identification Code).*
* *Direct Marketing Device Identifier (DM-DI): Direct marking is placing the UDI and, potentially the full UDI carrier, permanently on the device.*
* *Device Disposition/Current Location*: Where and in what state the device is at the time of the report, e.g. destroyed/lost or with manufacturer undergoing testing, or with original reporter, etc.

**Results of Product Owner’s Investigation**

* *Product Owner’s Device Analysis Results*: Specify, for this event, details of investigation methods, results and conclusions. The rationale for the course of action taken to investigate the incident should be included. The details of the actions to be completed and the timelines for their completion should be included. If no investigation is to be done, a rational needs to be provided here. The root cause should be identified. The root cause would ascertain the most likely reason why the problem occurred with the medical device. This may not be available at time of reporting.
* *Device History Review:* Includes a review of other similar events involving the same lot/batch, It should also include a review of device history records for each batch, lot or unit to ensure that the device was manufactured according to specifications, no anomalies during the manufacturing process etc.
* *Remedial Action/Corrective Action/Preventive Action*: Includes information on actions taken to correct the problem, including any post-market surveillance, recalls, or corrective or preventive actions and the design and manufacture of the device. This should also include the rationale for performing the corrective action. If no corrective action is to be taken, a rationale needs to be provided here. This may not be available at time of reporting.

[**IMDRF Adverse Event Terminology**](https://www.imdrf.org/documents/terminologies-categorized-adverse-event-reporting-aer-terms-terminology-and-codes)

Incidents should be coded to the most detailed level possible. The most appropriate code may be a level 1 or level 2 code depending on the circumstances and information known. It is likely that it will be necessary to use multiple terms from each annex in combination to adequately code the adverse event.

* *Annex A: Medical Device Problem* - Terms/codes for describing problems (malfunction, deterioration of function, failure) of medical devices that have occurred in pre- or post-market contexts (e.g. clinical studies, clinical evaluation or post-market surveillance). These terms allow capturing of the problems encountered at device(s) level through observational language without yet describing possible reasons or causes for the problems or failures observed.
* *Annex B: Cause Investigation* - Type of Investigation - Terms/codes for describing what was investigated and what kind of investigation was conducted to specify the root cause of the adverse event. Terms/Codes in this annex should be used to answer questions such as How was the investigation performed? Did it involve testing? Did it also or only involve non-testing means (e.g. interviews, etc.)
* *Annex C: Cause Investigation - Investigation Findings* - Terms/codes for describing the findings in the specific investigation that are the keys to identify the root cause. This annex has hierarchical levels, allowing jurisdictions to choose the level of coding to use. Terms/Codes in this annex should be used to answer the question What were the results of the investigation?
* *Annex D: Cause Investigation – Investigation Conclusion -* Terms/codes for describing the conclusion of the device involved in the reported event. Terms/Codes in this annex should be used to answer the question What is the conclusion regarding the root cause? (based on the results noted in the Investigation Findings and the way they were obtained noted in the Type of Investigation).
* *Annex E: Health Effects - Clinical Signs and Symptoms or Conditions -* Terms/codes for describing the clinical signs and symptoms or conditions of the affected person appearing as a result of the medical device adverse event/incident. These terms allow capturing of the patient signs and symptoms observed related to the medical device adverse event through observational language without using diagnostic specifics. These terms are largely based on a subset of \*MedDRA terms. This annex is organized along organ systems as well as physiological problems. The Level 1 term is mainly for organizational purposes and is expected to be too high level for coding purposes.

*\*The MedDRA® trademark is registered by ICH. This information/material is provided "as is" without warranty of any kind. In no event shall the ICH or the authors of the original information/material be liable for any claim, damages or other liability arising from or in connection with the use of this information/material.*

* *Annex F: Health Effects - Health Impact -* Terms/codes for describing the consequences of the medical device adverse event/incident on the person affected. Terms/Codes in this annex describe the resulting consequences of the medical device adverse event/incident on the person affected. The resulting consequences can include final patient outcomes and/or interventions or procedures required as a result of the clinical signs, symptoms and conditions captured using Annex E.
* *Annex G: Medical Device Component -* Terms/codes for describing the parts and components which were involved in, or affected by, the medical device adverse event/incident. These terms allow capturing of the specific part or component of the medical device which was involved in the incident. In the case that a component is also a stand-alone device, the Annex G term should not be used.