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|  | **Medical Device Adverse Event Reporting Form**  **for Medical Device Dealers** | MDAR1 Form Last revised1 October 2018 |
| 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. | | | |

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| **MANDATORY MEDICAL DEVICE ADVERSE EVENT REPORTING FORM** | |
| I – GENERAL INFORMATION | |
| HSA Adverse Event Reference No. |  |
| Product Owner Reference No. |  |
| Report Type *(please select one)* | Initial  Follow-up  Final  Trend |
| AE Category *(please select one)* | 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 |  |

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| 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. |  | | | |
| Software version |  | | | |
| Accessories/Associated Devices affected (if any) |  | | | |
| GMDN Code |  | | | |
| GMDN Term |  | | | |
| Product Owner Name |  | | | |
| Product Owner Address |  | | | |
| IV – DESCRIPTION OF EVENT | | | | |
| Device Operator *(please select one)* | 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 (%) |
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| 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 (%) |
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| 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 – 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)* |  | | | |
| Gender |  | | | |
| 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 |  | | | |
| Address |  | | | |
| Contact Name at site of event |  | | | |
| Job title |  | | | |
| Tel no. |  | | | |
| Email Address |  | | | |
| VIII – OTHER INFORMATION | | | | |
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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.
* *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.