**Medical Device Adverse Event Report – For use by Industry**

|  |  |
| --- | --- |
| **I - Administrative Information**  **Report Type (select one)**  Initial **:**  Follow up **:**  Final **:**  **Report Category**  Death/Serious Injury**:**  Other**:**  Date of this report:  Date of adverse event:  Date manufacturer aware:  **Person Submitting This Report**  Name:  Company:  Address:  Tel: Fax:  E-mail:  Identify all other Regulatory Authorities, where this report was also sent:  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **II - Clinical Event Information**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Description of event or problem**  If the device is an implantable device indicate both implant date and explant dates: (Known)  Implant Date:\_\_\_\_\_\_\_\_\_\_\_ Explant Date:\_\_\_\_\_\_\_\_\_\_ | **III - Healthcare Facility Information**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  Name:  Address:  Tel: Fax:  E-mail:  Contact name at site of the event:  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **IV - Device Information** (Primary Device)  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Generic Device Information**  Device WAND number:  GMDN Code:  GMDN Code Text (eg, catheters, central venous, peripherally inserted):  **Specific Device Information**  Brand Name:  Model #:  Software version:  Ser. Or Lot #s:  Manufacturer:  Contact Name:  Address:  Tel: Fax:  E-mail:  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Operator of Device at Time of Event**  HCP  Other Caregiver  Patient  N/A  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Usage of Device**  Single use **:**  Reuse of single Use**:**  Reuse of Reusable**:**  Re-serviced/Refurbished**:**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  Device Disposition/Current Location: |

|  |  |
| --- | --- |
| **V - Results of Manufacturer’s Investigation**  **Manufacturer’s Device Analysis Result**  (Specify, for this event, details of investigation method, results, and conclusions):  **Remedial Action/Corrective Action/Preventive Action**  (Specify if/what action was taken for the reported specific event or products. Include what action was taken to prevent recurrence. Clarify the timeframe for completion of action plans): | **VI - Patient Information**  Age:\_\_\_\_\_\_\_ M/F:\_\_\_\_\_\_\_\_ Wt. (kg):\_\_\_\_\_\_  **Patient focused Resolution of Event and Outcomes**  Corrective action taken relevant to the care of the patient:  Patient history (co-morbidities & medication):  Patient outcome:  List of other devices involved in the event:  If other implants involved – list brand, model & WAND number.  **VII - Other Reporting Information**  Mfr/sponsor aware of other similar events? (number or rate):  Country where these similar adverse events occurred:  Additional comments:  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  Submitting this report:  Compliance Management Branch, Medsafe, PO Box 5013, Wellington, 6145.  Email: [devices@moh.govt.nz](mailto:devices@moh.govt.nz) |

# Guidance on how to complete this form

Please answer every question with an appropriate answer, N/A (not applicable) or N/K (not known at this time).

If some of the applicable information required in this form is not available by the time the deadline (2, 10, or 30 days) for the particular category of report has expired, a report should be submitted containing all the available information. Such a report should be marked “initial” in Section I.

The form may be filled long-hand or electronically using Word®. The form can then be submitted by mail or saved and attached to an email and sent to devices@moh.govt.nz. ***This instructions page should not be included in the submission.*** The following provides some guidance on what information is required in some parts of the form. It is envisaged that the fields not mentioned in this explanatory note are self-explanatory.

## Section I – Administrative Information

***Report Type, Initial:*** The first report that the reporter (sponsor, manufacturer) is submitting about an event. The reporter expects to have to submit further information about the event at a later date.

***Report Type, Follow-up:*** Additional information to a previous (initial, follow-up or final) report.

***Report Type, Final:***The last report that the reporter expects to submit about an event. It is possible for the final report to also be the initial report about an event. If so, please indicate by crossing both boxes.

***Report Type, Trend****:* Under Quality Management System requirements, the manufacturer is expected to monitor trends of significant adverse events. Significant changes in frequency of occurrence or severity of events associated with devices must be reported. These reports are called “trend” reports.

***Report Category, Death/Serious Injury****:* Choose this category where the event resulted in the death or serious injury of a patient, user or other person.

***Report Category, Other****:* Choose this category where the event was a “near miss” or is the result of testing or other analysis and an event or further occurrence could lead to the death or serious injury of a patient, user or other person.

## Section II – Clinical Event Information

Provide as much detail about the event as possible, including what happened and what led up to the event (eg, the type of surgery or treatment). If the device is implantable, provide date of implant & explant.

## Section IV - Device Information

***WAND number#:*** The WAND number assigned to the device

***GMDN Code & Text:*** Global Medical Device Nomenclature (GMDN) Code and explanatory text, (eg, 40589 – clamp, surgical tubing, single use).

***Mfr name:*** Name of manufacturer

***Device Disposition/Current Location:*** Where and in what state the device is at the time of the report – eg, destroyed/lost or with manufacturer undergoing testing, or with original reporter, etc.

## Section VI – Patient Information

(Note: in some cases, the patient’s age gender and/or weight will be irrelevant. In others this information will be essential – eg, weight of patient in regards to orthopaedic implants – The reporter should exercise judgement when filling these fields.)

***List of other devices involved in the event:***  Some events are caused by the combined action of two or more devices. List any other device(s) and their WAND Number that was/were being used at the time of the event if known.

## Section VII - Other Reporting Information

***Mfr/Sponsor aware of other similar events? (# or rate):*** If there have been other similar events reported to either the sponsor or the manufacturer enter the number or rate. The rate should preferably be provided in the form of an incidence rate, for example: 0.4%, the number should include the number sold, for example, 12 of 3,000 units sold over two years in New Zealand or 25 of 5 million units sold over 5 years worldwide. If none, write “0” or “nil”.

When submitting a final report this section must be completed. This information will be requested if it is not provided at the time of the final report.