

**MDV001-02 Appendix 1 Version 1**

**Healthcare Professionals**

**Medical Device Incident Report Form**

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| --- | --- |
| **Section A: Details of Reporter**  **Tick the box if you wish to keep the below information confidential.** | |
| Name & Surname |  |
| Contact Number |  |
| Position |  |
| Email Address |  |
| Signature of Reporter |  |
| Date |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Section B: Incident Details** | | | | | | |
| **A1. Place of Incident** | | | | | | |
| Entity/ Hospital |  | | | | | |
| **A2. Device Details -** *Please include all the known/ visible details of the device* | | | | | | |
| Brand Name |  | | | | | |
| Product Code/ Reference (Ref) |  | | | | | |
| CPSU Sage Ref Number[[1]](#footnote-2) (if applicable) |  | | | | | |
| Batch/Lot Number |  | | Quantity known to be defective (if any) | | |  |
| Manufacturer |  | | | | | |
| Is the product CE Marked | Yes  No | | Sterile | | | Yes  No |
| **A sample of the defective device must be retained where possible.**  **If a sample cannot be retained, support this report with photos.** | | | | | | |
| Has a sample been retained? | Yes  No | If ‘NO’ specify reason: | | | | |
| **A3. Incident Details** | | | | | | |
| Date of Incident (DD-MM-YYYY) |  | Name of the ward/unit of where the incident occurred | | |  | |
| Functional Use of Product |  | | | | | |
| Was the device used in combination with other medical devices? | | | | Yes  No | | |
| If ‘Yes’, add all relevant details of other products | Brand name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  CPSU Ref Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Product Code/Reference (Ref): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Serial/ Batch/ Lot Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | |
| Was the device used in combination with a medicinal product? | | | | Yes  No | | |
| If ‘Yes’ add all relevant details of other products | Brand name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Batch Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Other (e.g. dose/ flow rate): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | |
| Was a serious incident[[2]](#footnote-3) suffered? | ☐ Yes ☐ No | | | | | |
| If ‘Yes’, indicate the type of incident:  Causal relationship between the incident and the medical device  Serious public health threat  Death of a patient, user or other person  Unanticipated serious deterioration in a person’s state of health  Other (please specify): | | | | | | |
| Classify the severity of the incident | High Risk  Medium Risk  Low Risk | | | | | |
| **Description of Incident:**  *If a sample cannot be retained, support this report with photos or any other relevant information.* | | | | | | |
| **Other comments:** | | | | | | |

**Data Protection Consent Statement**

*The person putting forward the report hereby consents to the processing of personal data by the Malta Medicines Authority and understands that this data shall be processed in accordance with the General Data Protection Regulation (GDPR), Regulation 2016/679/EU of the European Parliament and of the Council of 27 April 2016, the Data Protection Act (Chapter 586 of the Laws of Malta) and the Malta Medicines Authority Data Protection Policy (P-MA05). The applicant also understands that the Malta Medicines Authority shall process this personal data in line with the purposes they are collected for in this form.*

1. *To liaise with store officer to attain SCODE Reference Number* [↑](#footnote-ref-2)
2. serious incident’ means any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat. [↑](#footnote-ref-3)