

**Healthcare Professionals**

**MT-MDF08 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 |  |

|  |  |  |  |  |  |  |  |
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| **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 |  | | | | | | |
| Generic 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): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | |
| ***Definition of ‘incident’ as per EU Regulations:***  For **medical devices**: ***‘incident’*** means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect*. [Regulation (EU) 2017/745 (MDR) Article 2(64)]*  For ***in vitro* diagnostic medical devices: ‘incident’** means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any harm as a consequence of a medical decision, action taken or not taken on the basis of information or result(s) provided by the device. *[Regulation (EU) 2017/746 (IVDR) Article 2(67)]*  *End-user is kindly requested to fill in each field, with additional comments if (b) and (c) are in the affirmative.* | | | | | | | |
|  | | | | | | | |
| **Has the incident, directly or indirectly led, might have led or might lead to any of the following:** | | | | | | | Indicate if:  YES / NO |
|  | | | | | | | |
| (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;  [*‘serious public health threat’ means an event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time.* [MDR Article 2(66); IVDR Article 2(69)] | | | | | | |  |
| Further comments: | | | | | | | |

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| **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, repealing Directive 95/46 EC, 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.*

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**Malta Medicines Authority Declaration for Form Submission**

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I, the applicant, declare that all information given in the application form is true, complete and correct. I also bind myself to inform immediately any change to details in the application form and annexes, where relevant, to the Malta Medicines Authority.

Company Name (if applicable): Click here to enter text.

Name & Surname: Click here to enter text.

Position: Click here to enter text.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: Click to enter a date.

1. *To liaise with store officer to attain SCODE Reference Number* [↑](#footnote-ref-2)