

**MDV001-02 Appendix 2 Version 1**

**Member of the Public 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 | |  | |
| Email Address | |  | |
| Date | |  | |
| **Section B: Details of the medical device.**  *Please include all the known/ visible details of the device* | | | |
| Name of Device | | |  |
| Intended Use of the medical device  (Example: blood glucose meter to monitor glucose levels) | | |  |
| Name of Manufacturer | | |  |
| Batch Number / Lot Number | | |  |
| Device obtained from: | | | Public Institution  Private Institution  Pharmacy  Online  Other  If Other, please specify:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Name of institution / outlet | | |  |
| Address (if known) | | |  |
| Telephone (if known) | | |  |
| **Section C: Incident Details** | | | |
| Date of Incident (DD-MM-YYYY) |  | | |
| **Description of Incident:**  *If a sample cannot be retained, support this report with photos or any other relevant information* | | | |
| Was the device retained? | | | Yes  No |
| Was an injury incurred? | | | Yes  No |
| If ‘Yes’, description of injury: | | | |

**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.*