



MALTA

MEDICINES
AUTHORITY

Guidance for the Medical Devices Incident Report Form – Healthcare Professionals

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Medical Devices & Pharmaceutical Collaboration Directorate

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1. Introduction

The Healthcare Professionals (HCPs) medical devices incident report form is being presented by the Malta Medicines Authority (MMA) for the management of safety issue reports related to all medical devices made available on the local market.

2. Scope

The *Medical Devices Incident Report Form - Healthcare Professionals* ensures timely and appropriate reporting of incidents related to medical devices, in accordance with European and local legislation.

This guidance document provides comprehensive instructions to healthcare professionals when reporting an incident or a deficiency related to the medical device product to the National Competent Authority.

3. Terms, Definitions and Abbreviations

CE marking

A marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in the Regulations (EU) 2017/745 and (EU) 2017/746 and other applicable Union harmonisation legislation providing for its affixing.

Incident

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.

Manufacturer

A natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.

Medical Device

Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Note: The term 'medical device' in this guidance documents also refers to in-vitro diagnostics.

Serious Incident

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.

User

Any healthcare professional or lay person who uses a device.

e-form: Electronic Form

HCP: Healthcare Professional

GDPR: General Data Protection Regulation

MMA: Malta Medicines Authority

4. Specific Guidance

4.1 Individuals reporting through the HCPs Medical Devices Incident Form

The medical devices incident report form may be solely referred to and utilised by healthcare professionals working in the public and private sector.

4.2 General Details related to the reporting process

4.2.1 Reporting Form Title

MT-MDF08 - Medical Device Incident Report Form - Healthcare Professionals, related to this guidance document, may be downloaded from the MMA website <https://medicinesauthority.gov.mt/>, under the section for medical devices.

4.2.2 E-Form

The incident form is an e-form which must be filled in electronically using the space provided. Handwritten forms will not be accepted. The completed e-form and supported documentation must be sent electronically to devices.medicinesauthority@gov.mt.

4.2.3 Acknowledgement

Once the incident reporting form has been successfully received and reviewed, an acknowledgment will be sent to the reporter's electronic address provided.

4.2.4 Official Languages

The official languages in Malta are Maltese and English. All application forms and supporting documentation for the registration process must be completed in either Maltese or English.

4.3 Filling in the Incident Reporting Form

All sections must be completed by the healthcare professional.

The Medical Devices Incident Report Form is divided in the following sections:

- Section A: Incident Details
- Section B: Reporter's Details
- Data Protection Consent Statement
- Malta Medicines Authority Declaration for Form Submission

4.3.1 Section A: Reporter's Details.

The HCP putting forward the incident report shall input the following details:

- Contact Name & Surname
- Contact Number
- Designation
- Email Address
- Signature
- Date

4.3.2 Section B: Incident Details

This section is divided into three sections:

4.3.2.1 Place of Incident

The reporter shall clearly state where the incident took place.

4.3.2.2 Device Details

The reporter must include all known and visible details of the device being reported.

- Brand Name
- Product Code or Reference
- CPSU Sage Code Reference Number (if applicable)
- Batch/Lot Number
- Quantity known to be defective (if any)
- Manufacturer details
- If the product is CE marked or not
- If the product is sterile or not
- If a sample is retained or not

4.3.2.3 Incident Details

The reporter shall provide clear information of the following:

- Date of Incident in a pre-indicated format of dd/mm/yyyy
- Name of the ward/unit where the incident occurred
- Functional use of product
- If the device was used in combination with other medical devices or not
- If the device was used in combination with a medicinal product or not
- If a serious incident was suffered or not
- Selecting the type of incident
- Indicating the nature of the severity of the incident
- Description of the incident
- Other comments (if any)

4.4 Data Protection Consent Statement

The person putting forward the report shall confirm consent, by ticking the box in this section, to the processing of personal data by the MMA and understands that this data shall be processed in accordance with the General Data Protection Regulation (GDPR).

5. References

Cap 458 Act no VII of 2020, An Act to amend the Medicines Act

<https://legislation.mt/eli/act/2020/7/eng>

S.L. 458.59 Medical Devices and In-Vitro Diagnostic Medical Devices Provision On The Maltese Market Regulations

<https://legislation.mt/eli/sl/458.59/eng>

Legal Notice 321 Medical Devices and In-Vitro Diagnostic Medical Devices Provision on the Maltese Market Regulations, 2020

<https://legislation.mt/eli/lv/2020/321/eng>

EU legislations- Medical Devices and In-Vitro Diagnostic Medical Devices

https://health.ec.europa.eu/medical-devices-sector/new-regulations_en

Approvals on file

List of Appendices

N/A