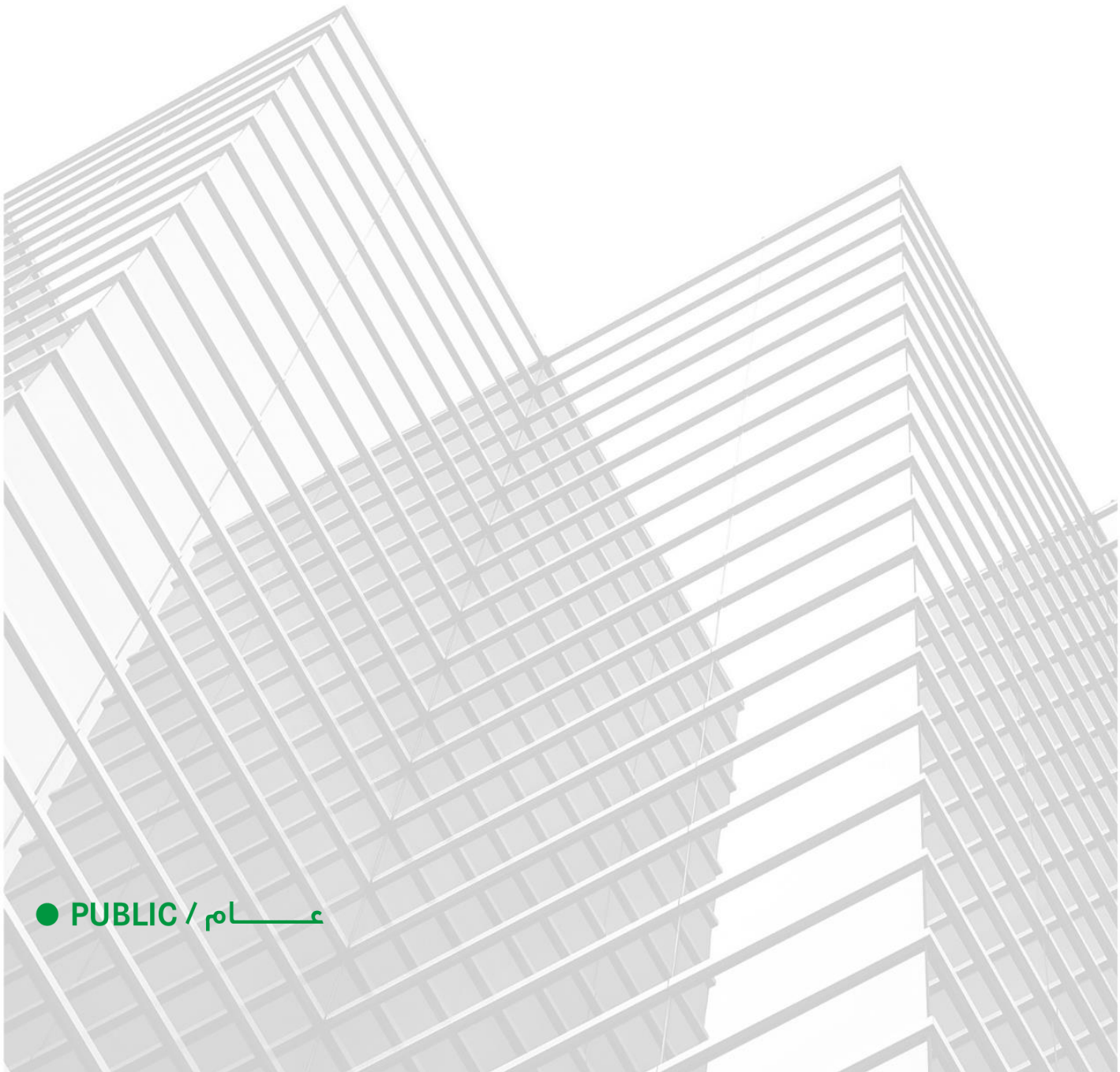
دائـــرة الـصـحـــة
DEPARTMENT OF HEALTH

STANDARD ON MEDICAL DEVICE REPORTING (MDR)



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Applies To:	All Healthcare Professionals and Healthcare Providers in the Emirate of Abu Dhabi. - Medical device manufacturers, marketing authorization holder, importers, authorized agents/ representatives, distributors suppliers and registrants of medical device or any other person who is responsible for placing the device on the market.		
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1. Standard Scope

The purpose of this standard is to set the requirements of reporting medical device problems, medical device incidents & adverse events of medical devices marketed/available in the Emirate of Abu Dhabi.

The standard is applicable to all healthcare providers & professionals in the Emirate of Abu Dhabi. Furthermore; to medical device manufacturers, marketing authorization holders/ representatives, importers, authorized agents, distributors, suppliers and registrants or any other person who is responsible for placing the device on the market.

2. Definitions and Abbreviations

No.	Term / Abbreviation	Definition
2.1	Medical Device[1,2]	A medical device can be any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose. Medical devices are health or medical instruments used to treat, mitigate, diagnose or prevent a disease or abnormal physical condition. Devices range from adhesive bandages, toothbrushes and contact lenses to complex devices, such as x-ray units, insulin pumps and pacemakers. They also include in vitro diagnostic devices, such as cancer screening tests, blood glucose monitors and pregnancy test kits.
2.2	Healthcare Provider[3]	Any person who operates a healthcare facility or in selected instance, who proposes to do so. For these purposes: • 'person' means any individual or legal entity, that person 'operates' a healthcare facility if he carries on the business of providing healthcare services at the facility or, • where healthcare services are not provided as part of a business, otherwise has the ultimate responsibility for the management of the facility.
2.3	Healthcare Professional	An individual who provides clinical professional services within a named healthcare profession.
2.4	Medical device adverse event reporting[4]	An unexpected event that occurs during or result from 'patient use' of a medical device.

2.5	Serious adverse events[5]	A serious adverse event is any undesirable experience associated with the use of a medical product in a patient resulting in at least one of the following: • Death • Life-threatening condition • Hospitalization (initial or prolonged) • Disability or Permanent Damage • Congenital Anomaly/Birth Defect • Required Intervention to Prevent Permanent Impairment of a body function or permanent Damage to a body structure. • Other serious events that do not fit the above outcomes, but may jeopardize the patient and may require medical or surgical intervention (treatment) to prevent one of the above outcomes.

3. Standard Requirements and Specifications

3. Reporting Requirements:
The report of the event should contain as much detail as possible, and should not be delayed for any reason

3.1 Below table summarize Reporting Requirements with the time frame.

	WHAT TO REPORT	WHEN	TO WHOM	REPORT FORM
Healthcare Providers/ Professionals	1.Deaths, serious injuries and malfunctions	1.Within 24 hours of becoming aware of an event	DOH Pharmacovigilance & Drug Education at PVE@doh.gov.ae & manufacturer/ distributors	Online PDF Form refer to appendix No.1
	2. Event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health	2. No later than 5 days after the day that you become aware of a reportable event		
	3. Other medical device reports with no urgent safety impact e.g. Incident Report, use errors, product quality issues, and therapeutic failures or any device product problems	3. Expedited reporting is required but in no case later than 15 days.	DOH Pharmacovigilance & Drug Education at PVE@doh.gov.ae & manufacturer/ distributors	

Manufacturers, marketing authorization holder, importers, authorized agents/ representatives, distributors, suppliers and registrants or any other person who is responsible for placing the device on the market	1.Deaths, serious injuries and malfunctions 2. Event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health	1 & 2: Within 5 days of becoming aware of an event	DOH Pharmacovigilance & Drug Education PVE@doh.gov.ae	Online PDF Form refer to appendix No. 2
	3.Other Medical device reports with no urgent safety impact e.g. Incident Report, use errors, product quality issues, and therapeutic failures or any device product problems	3. Expedited reporting is required but in no case later than 15 days.		

3.2 Further requirements for the manufacturers, importers, distributors, authorized agents/representatives & any other person who is responsible for placing the device on the market

3.2.1 Assessing the link between the device and the event, the manufacturers, importers, distributors, authorized agents/representatives & any other person who is responsible for placing the device on the market should consider:

- The opinion, based on available information, from a healthcare professional;
- Information concerning previous, similar events;
- Other information held by the manufacturer.

3.2.2 manufacturers, importers, distributors, authorized agent/representatives & any other person who is responsible for placing the device on the market are responsible for obtaining and providing DOH PV program with any information that is missing from the reports that are received from healthcare providers, professionals, and other initial reporters.

3.2.3 Manufacturers, importers, distributors, authorized agent/representatives & any other person who is responsible for placing the device on the market are required to submit, within one month after receipt any required information regarding deaths, serious injuries, and malfunctions that was not available to them when the initial report was submitted.

3.3 MDR Reporting Specifications

3.3.1 A PDF fillable reporting form is accessible at DOH website via the following link: https://www.doh.gov.ae/en/resources/Reporting

3.3.2 Applicable sections of the MDR form should be filled in as complete as possible.

3.3.3 DOH will acknowledge the receipt of MDR. Any follow up of a reported MDR should be made by mentioning the 'unique report number' provided to the reporter

3.3.4 Any information related to the identity of the patient and/or the reporter of the MDR will be protected to the fullest extent of law and will not be used in any way against him.

3.3.5 DOH may provide the reporter with recommendations to initiate further actions on the reported cases if necessary.

3.3.6 Important safety concerns emerging from MDR reports will be communicated to healthcare professionals/providers through circulars, alerts or advisories as deemed necessary by DOH.

3.3.7 For enquiries on MDR reporting, contact:

Department of Health Abu Dhabi/ Zayed Herbal Complex Division
Pharmacovigilance & Drug education E-mail PVE@doh.gov.ae
Phone: 02 419 1170 /3576.

4. Key Stakeholder Roles and Responsibilities

4. Duties of Healthcare Providers, Healthcare Professionals, Medical device manufacturers, marketing authorization holders, importers, authorized agents/representatives, distributors, suppliers and registrants or any other person who is responsible for placing the device on the market.

4.1. **Healthcare Providers should:**

4.1.1 Develop policies and procedures and implement mechanisms to identify, document and report any serious adverse events that may be associated directly or indirectly with a medical device, as well as use errors, incident, product quality issues, and therapeutic failures to the Department of Health (DOH) Pharmacovigilance Program.

4.1.2 Report a suspected medical device-related death to both the DOH and the manufacturer or supplier, authorized agent/representative, distributor, registrants or any other person who is responsible for placing the device on the market.

4.2. **Healthcare professionals should:**

4.2.1 Report any serious adverse events that may be associated directly or indirectly with a medical device, as well as use errors, incidents, product quality issues, and therapeutic failures experienced from using medical device, soon after the adverse outcome or event occurred.

4.2.2 Document the MDR in the patient's medical record to prevent recurrence of the case whenever applicable.

4.2.3 Encourage patients to report to a healthcare professional any MDR experienced. Healthcare professionals can provide additional clinical information prior to sending reports to DOH which will make the reports more complete and scientifically valid.

Important notice: The submission of a Medical Device Report (MDR) itself is not evidence that the device caused or contributed to the adverse outcome or event.

4.3. **Medical device manufacturers, marketing authorization holders, importers, authorized agents/representatives, distributors, suppliers and registrants or any other person who is responsible for placing the device on the market:**

4.3.1 Mandatory reporting of serious medical device adverse events, medical device Incident reports and medical device product problems to DOH PV Program In the case of:

a. Any of their devices may have caused or contributed to a death or serious injury.
b. Become aware that their device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.
c. Any of their devices are suspected to have efficacy, quality or safety concerns.
d. Communicate decision on recalls, safety alert & safety update(s) related to the medical device with DOH PV program.

5. Monitoring and Evaluation

- All Healthcare Providers must develop policies and procedures and implement mechanisms to identify, document and report any serious adverse events that may be associated directly or indirectly with a medical device, as well as use errors, incident, product quality issues, and therapeutic failures to the Department of Health (DOH) Pharmacovigilance Program[1].

6. Enforcement and Sanctions

DOH may impose sanctions in relation to any breach of requirements under this standard in accordance with the Chapter on Complaints, Investigations, Regulatory Action and Sanctions Policy, Healthcare Regulator Manual.

[1] DOH Pharmacovigilance Reporting: https://www.doh.gov.ae/-/media/Feature/Research/Reports/Guidance-to-Access-Online-reporting.ashx

7. Relevant Reference Documents

No.	Reference Date	Reference Name	Relation Explanation / Coding / Publication Links
1	March 7th, 2022	WHO Medical devices	https://www.who.int/health-topics/medical-devices#tab=tab_1
2	March 7th, 2022	Health Canada, Health products	Reporting complaints about health products - Canada.ca
3	March 7th, 2022	DOH Healthcare Providers Manual	https://www.doh.gov.ae/-/media/7EA6916C486A4D6BBA0036C8CD931B11.ashx
4	March 7th, 2022	National Library of Medicine	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6786964/
5	March 7th, 2022	What is a Serious Adverse Event?	https://www.fda.gov/safety/medwatch/howtoreport/ucm053087.htm
6	March 7th, 2022	قانون اتحادي رقم (8) لسنة 2019، في شأن المنتجات الطبية ومهنة الصيدلة والمنشآت الصيدلانية	قانون اتحادي رقم (8) لسنة 2019، في شأن المنتجات الطبية ومهنة الصيدلة والمنشآت الصيدلانية (mohap.gov.ae)

8. APPENDICES

Appendix No.1: Medical Device Reporting Form for Healthcare Professional/Providers

Medical devices are health or medical instruments used to treat, mitigate, diagnose or prevent a disease or abnormal physical condition.
Devices range from adhesive bandages, toothbrushes and contact lenses to complex devices, such as x-ray units, insulin pumps and pacemakers. They also include in vitro diagnostic devices, such as cancer screening tests, blood glucose monitors and pregnancy test kits.

You are a:

1. Healthcare professional
2. Healthcare providers

What are you reporting about?

- MD Adverse Event
- Product Use
- Product Problem (e.g., defects/malfunctions)

1- About Patient information

- EID:
- Name: Gender:
- Date of birth: Age:
- Weight:
- Phone Number:
- Facility Name:

Can we send your personal details to the medical device manufacturer so they can contact you for more information? The manufacturer may need further information to help them investigate the problem and so not providing your personal details may limit their investigation.

- Yes
- No

2- About Device Information:

Please provide as much information about the device as possible

- Brand Name
- Common Device Name Procode
- Manufacturer Name
- Model # Lot #
- Catalog # Expiration Date (dd-mmm-yyyy)
- Serial # Unique Identifier (UDI) #

Operator of Device

- Health
- Professional
- Patient/Consumer
- Other

If Implanted, Give Date (dd-mmm-yyyy) If Explanted, Give Date (dd-mmm-yyyy)

Is this a single-use device that was reprocessed and reused on a patient?

- Yes
- No

Product Available for Evaluation?

- Yes
- No
- Returned to Manufacturer on (dd-mmm-yyyy)

Do you have a picture of the product? (check yes if you are including a picture)

- Yes / No
- Attachment

A. Who was using the device when the incident occurred? (Optional)
   - Healthcare Professional
   - User
   - Other, specify

B. Date of incident from (If you don't know the exact date choose the 1st of the month) YYYY/MM/DD

C. Was anybody harmed? (this includes indirect harm such as delays, misdiagnosis) Please select harm type from the list below, if no one was harmed please select 'No Health Consequences or Impact'

D. Any clinical signs, symptoms and conditions related to the incident (if applicable)

E. Please provide a description of the incident including any faults with the device or harm experienced by the patient. Please note attachments can be added for any additional information. Please do not include any personal data.

3- <u>About the person filling out this form</u>

- Name:
- Number:
- Email Address:
- Profession:
- Major:
- Facility Name:
- Did you report this problem to the company that makes this product? Yes / No

Appendix No.2: Medical Device Reporting Form for Manufacturers, marketing authorization holder, importers, authorized agents/ representatives, distributors, suppliers and registrants or any other person who is responsible for placing the device on the market

* Is there a patient involvement? □ Yes □ No

1. ADMINISTRATIVE INFORMATION

- *Report Type (select one):
  - Initial
  - Follow-up
  - Combined initial and final
  - Final

- *Date of this report (dd-mmm-yyyy)
- *Date of incident/adverse event (dd-mmm-yyyy)
- Responsible person awareness date (dd-mmm-yyyy)
- Manufacturer awareness date (dd-mmm-yyyy)
- Expected date of next report (dd-mmm-yyyy)
- *Report Reference Number (assigned by manufacturer for the case):

Information of the submitter of this report:

- *Submitter of the report:
  - Manufacturer
  - Authorized agent / representative
  - Importer
  - Distributor
  - Other, please specify
- *Name:
- Address:
- *Mobile Phone No:
- *E-mail:

Information of the initial reporter:

- Role of initial reporter:
  - Healthcare professional
  - Patient Lay user
  - Other, please specify

- Name of healthcare facility where incident occurred:
- Contact Information:

2. EVENT INFORMATION

- *Event Description:

- *No. of affected people involved:
- *No. of devices involved:

- *Does the incident represent a serious public health threat? □ Yes □ No

- *Consequences of Product problem(s): Serious: □ Yes □ No

- *If Serious Please indicate the reason of seriousness:
  - Patient Died

- Life threatening
- Hospitalization
- Prolonged Hospitalization
- Congenital Anomaly/Birth Defects
- Disability or Permanent Damage
- Required Intervention to Prevent Permanent Impairment/Damage
- Other, specify

- *Manufacturer/Sponsor aware of other similar events? (number or rate)

- IMDRF Medical device problem codes (Annex A)

	Choice 1 (most relevant)	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Medical device problem codes'	Code	Code	Code	Code	Code	Code

3. HEALTHCARE FACILITY INFORMATION

- Name of the Facility:
- Name of Contact Person:
- Address:
- Phone:
- E-mail:

4. DEVICE/PRODUCT INFORMATION

- *Brand Name:
- *Commercial Device Name:
- *Manufacturer Name:
- Product Registration No.
- *Model / Catalogue number
- *Serial No.
- *Lot / Batch No.
- Unique Identifier (UDI) No.
- Software version No. (if applicable)
- Device manufacturing date (dd-mmm-yyyy)
- Device expiry date (dd-mmm-yyyy)

- Type of Device (mark one only):

□ Active implantable devices
□ Administration& giving sets
□ Anesthetic machines& monitors
□ Anesthetic & breathing masks
□ Autoclaves
□ Bath aids
□ Beds& mattresses
□ Blood pressure measurement
□ Breast implant
□ Cardiovascular implants& devices
□ External defibrillators& pacemakers
□ Feeding tubes
□ Gloves
□ Guide wires
□ Hearing aids
□ Hypodermic Syringes& needles
□ Implant materials
□ Infant incubators
□ Infusion pumps, syringe drivers
□ Insulin syringes
□ Patient hoists
□ Physiotherapy equipment
□ Radiotherapy equipment
□ Radionuclide equipment
□ Resuscitators
□ Stapler& staples
□ Stretchers
□ Surgical instruments
□ Surgical powder
□ Sutures

□ Commodes
□ Contact Lenses& care Products
□ CT systems
□ Dental materials& applications
□ Dialysis equipment
□ Diathermy equipment& accessories
□ Dressings
□ Endoscopes& accessories
□ Endotracheal tubes& airways
□ Ophthalmic equipment
□ Intravenous catheters& cannula
□ IVD (In Vitro Diagnostic) device
□ Joint prostheses
□ Lasers& accessories
□ Magnetic resonance equipment& accessories
□ Mobile x-ray systems
□ Monitor& electrodes
□ Non-active implants
□ Thermometers
□ Ultrasound equipment
□ Urinary catheters
□ Ventilators
□ Walking Sticks/ Frames
□ Wound drains
□ X-ray equipment systems& accessories
□ Others (Please specify):

For implants only:

- Implant date (dd/mm/yyyy):
- Explant date (dd/mm/yyyy):
- Duration of implantation (to be filled if the exact implant and explant dates are unknown)

- Device Available for Evaluation?
  - Yes
  - No
  - Returned to Manufacturer on (dd-mmm-yyyy):

- Usage of Medical Device:
  - Initial use
  - Reuse of single use medical device
  - Reuse of reusable medical device
  - Re-serviced/Refurbished
  - Problem noted prior to use
  - Others, Specify

- *Operator of medical device at the time of the event (select one)
  - Health Professional
  - Patient
  - Others

- *Device Disposition / Current Location:

5. RESULT OF MANUAFCTURER'S INVESTIGATION

- *Manufacturer's preliminary comments:
  o for initial and follow-up reports: preliminary results and conclusions of manufacturer's investigation:

  o Initial actions (corrective and/or preventive) implemented by the manufacturer:

- *Cause investigation and conclusion
  o For Final (Reportable incident): Description of the manufacturer's evaluation concerning possible root causes/causative factors and conclusion:

- IMDRF 'Cause Investigation' terms and codes (Annex B, C, D)

5. INFORMATION OF PATIENT

	Choice 1 (most relevant)	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6	Choice 7	Choice 8
IMDRF Cause investigation: Type of investigation (Annex B)	Code	Code	Code	Code	Code	Code	Code	Code
IMDRF Cause investigation: Investigation findings (Annex C)	Code	Code	Code	Code	Code	Code		
IMDRF Cause investigation: Investigation conclusion (Annex D)	Code	Code	Code	Code	Code	Code		

- IMDRF 'Health Effect' terms and codes (Annex E, F)

	Choice 1 *(most relevant)*	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Clinical signs, symptoms, and conditions codes' (Annex E)	Code	Code	Code	Code	Code	Code
IMDRF 'Health impact' codes (Annex F)	Code	Code	Code	Code	Code	Code

- Age at time of event (months, years):
- Gender (M/F):
- Weight (kg):
- *Corrective action taken relevant to the care of the patient:
- *Patient outcome:

6. COMMENTS

*Fields are mandatory.

The Required Data and Information for Reporting MD with No patient involvement

- Report Type
- Reporter Name
- Reporter email
- Reporter mobile
- Date of Submission (m/d/y)
- Date of incident (m/d/y)
- Manufacturer awareness date (m/d/y)
- Device/Product Name
- Manufacturer Name
- Model
- Serial Number
- Lot number
- Incident/problem Description
- Health impact
- Result