MEDICAL DEVICES SECTOR

Guidance document for Manufacturers, Authorized Representative, Importers & Distributors about Reporting System

Department of Surveillance & Biometrics
Medical Devices Sector Mission

Our mission is to ensure safety, efficacy, and quality of medical devices and their performance according to their intended purpose, and to ensure the safety of related electronic products.
**FOREWORD**

Guidance document is a set of implementing rules assist the Manufacturers, Authorized representatives, Importers and Distributors to report any adverse event or recalls into the National Center for Medical Devices Reporting (NCMDR).

This guidance document is one of a series that has been produced to help explain the guidance for medical devices reporting in Kingdom of Saudi Arabia.

As a corollary to the above, it is equally important to note that MDS – SFDA reserves the right to request information or material, or define conditions not specially described in this document, in order to allow the sector to ensure safety, efficacy, and quality of medical devices and their performance according to their intended purpose, and to ensure the safety of related electronic products.

MDS – SFDA is committed to ensuring that such requests are justifiable.
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1. Introduction

In accordance with the royal decree issued on 25/01/1428H (13 February 2007) which assigned the responsibility for regulating medical devices, in vitro diagnostic devices, prescription eye glasses, contact lenses and their solutions to the Saudi Food and Drug Authority (SFDA). And the council of ministers decree No. 181 on 03/06/1428H (18 June 2007) which gives the SFDA full authority to issue guidance that include rules and procedures of registering medical devices establishments and their products. The Saudi Food & Drug authority (SFDA) is responsible for Protect and maintain public health within the KSA by the implementation of provisions ensuring a high level of safety and health protection of patients, users and third parties with regard to the use of medical devices as it relates to their manufacture, supply and use during their lifecycle and mandate measures, and allocate responsibilities, to ensure that medical devices placed on the market and/or put into service within the KSA comply with all relevant provisions of the Interim Regulation. To do so it maintains an up-to-date database on medical devices recalls and adverse events. The database includes products manufactured in or imported into the Kingdom of Saudi Arabia (KSA). SFDA also works closely with hospitals and healthcare providers to help them take appropriate corrective action.

(Figure 1): NCMDR website
1.1 Definitions

Medical Device:

means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:

1) Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;

and

2) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.
**In Vitro Diagnostic Devices:**

means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software and related instruments or apparatus or other articles.

**Medical Devices Accessories**

means a product intended specifically by its manufacturer to be used together with a medical device to enable that medical device to achieve its intended purpose.

**Establishment**

any place of business within the KSA that is involved in the manufacture, and/or placing on the market, and/or distribution of medical devices; or acting on behalf of the manufacturer.

**Manufacturer**

means any natural or legal person with responsibility for design and manufacture of a medical device with the intention of making it available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person.

**Authorized representative**

means any natural or legal person established within the KSA who has received a written mandate from the manufacturer to act on his behalf for specified tasks including the obligation to represent the manufacturer in its dealings with the SFDA.
**Importer**

means any natural or legal person in the supply chain who is the first to make a medical device, manufactured in another jurisdiction, available in the KSA.

**Distributor**

means any natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user.

**Medical Devices sector (SFDA - MDS):**

The government entity that is legally responsible for establishment licensing involved in manufacturing, importing and distributing of medical devices within the KSA, maintaining liaison with similar regulatory entities in other nations, and collecting and providing information and related educational support related to medical devices to the Saudi health community in accordance with a Royal Decree issued on 25 Muharram 1428 H (13 February 2007).

**1.2 Device Identification**

**Type:** a kind, class, or category of medical devices, all of which have something in common, due to its importance of unified nomenclature on identifying medical devices SFDA works with Global Harmonization Task Force (GHFT) which include in its membership USA, Canada, Japan, Australia and EU also SFDA works with Asian Harmonization Working Party (AHWP) which include in its membership more than 16 countries in order to achieve harmonization in this essential part throughout all economy members throughout for adapting recognized International medical devices nomenclature.

**Brand:** The name of the commercial entity that manufactures and/or distributes the product, such as Phillips, Terumo, or Alaris.
**Model:** The designation of the specific product and its unique design and functional characteristics. The model designation may be in plain language, alphabetic or numeric characters, or combinations thereof—for example: Model Cardio 2 or Model RE-12. Manufacturers and importers are inconsistent in assigning model designations. They sometimes assign the same model designation to different devices sold in different countries or different designations to the identical device sold in different countries. For purpose of SFDA reporting, please use the model number on the labeling (written, printed or graphic matter)

**It includes following :**
1. affixed to a medical device or any of its containers or wrappers.
2. information accompanying a medical device, related to identification, technical description.
3. information accompanying a medical device, related to its use, but excluding shipping documents.

**Serial number:** The unique numeric or alphanumeric identifier assigned by the manufacturer to each individual device. Depending on the type of product, the serial number may be found on a nomenclature plate, a chassis, or on the device packaging. Single-use products often lack such identification, and with some single-use products such as orthopedic implants, the model and lot numbers may be found on the packaging, which should not be discarded until the model and lot information is recorded in the individual patient’s chart. This information may prove critical for tracking the product and patient in the event of a product recall from the market.

**Control Number:** The control number is a unique number or alphanumeric sequence assigned to a specific device by the healthcare facilities or its contractors for the purpose of inventory, property, and maintenance management. The control number is never duplicated or reassigned. When the device is scrapped, the number is permanently removed.
1.3 The National Center for Medical Devices Reporting (NCMDR)

Organization managing a database devoted to receive adverse event reports about any medical devices malfunction from hospitals and healthcare facilities all around KSA, studying them and working together with manufacturers, authorized representatives, importers and distributors to take the right action and assuring the safe performance.

1.4 Goals of NCMDR

Establishment of NCMDR was in order to achieve following goals to:

- Improve protection of the health and safety of patients, users and others.
- Disseminate relevant device related information which may reduce the likelihood of, or prevent repetition of adverse events, or alleviate consequences of such repetition.
- Execute a key aspect of the SFDA’s post-market activities.
- Encourage collaboration between manufacturers and health care facilities to identify and investigate adverse events associated with medical devices and take appropriate action.
- Encourage the reporting of adverse events by medical device institutions and users, manufacturers, authorized representatives and organizations involved in supplying medical devices to the KSA.
- Provide a database of information on the safety and performance of medical devices that is suitable for the exchange of adverse events information with other Regulatory Authorities.

1.5 Importance of NCMDR

As part of its public mandate to protect patients and health professionals, the Saudi Food and Drug Authority (SFDA) maintains an online national medical devices reporting system. The purpose of this system is to identify events in which:

- Patients, health care practitioners, or other persons may have suffered harm as a result of failure or use error of a medical devices.
• A medical devices failure may have harmed the environment.
• A significant medical devices failure may be likely to recur and which may harm patients, users or the environment.

➢ What is a recall?

A recall is an action taken to address a problem with a medical device that violates SFDA law. Recall occurs when a medical device is defective, when it could be a risk to health, or when it is both defective and a risk to health.

A medical device recall does not always mean that you must stop using the medical device or return it to the company. A recall sometimes means that the medical device needs to be checked, adjusted, or fixed. (For example, if implanted device is recalled, it does not always need to be removed. When an implanted device has the potential to fail unexpectedly, companies often advise doctors to contact their patients to discuss the risk of removing the device compared to the risk of leaving it in place).

Examples of the types of actions that may be considered recalls:

• Inspecting the device for problems
• Repairing the device
• Adjusting settings on the device
• Re-labeling the device
• Destroying device
• Notifying patients of a problem
• Monitoring patients for health issues

Sometimes a company may have concerns about a group of products, but it cannot predict which individual devices will be affected. To be on the safe side, the company may recall an entire lot, model, or product line.

A recall is either a Correction or a Removal depending on where the action takes place.
**Correction** - Addresses a problem with a medical device in the place where it is used or sold.

**Removal** - Addresses a problem with a medical device by removing it from where it is used or sold.

- Who recalls medical device?

In most cases, a company (Manufacturers, authorized representatives, importers and distributors, or other responsible party) recalls a medical device on its own (voluntarily). When a company becomes aware that one of its medical devices violates SFDA law,

1. It recalls the device (through Correction or Removal actions); and
2. Notifies SFDA.

Legally, SFDA can require a company to recall a device. This could happen if a company refuses to recall a device that is associated with significant health problems or death.

**What is medical device adverse event?**

It is the report of any event that lead or might lead to undesired or unexpected issues regarding safety of patients, users, janitors or any other person. This may include the following:

- Problems with the design of the device.
- Untrained or unaware staff.
- Use error.
- Uninstructed modification.
- Inadequate maintenance.
- Inappropriate conditions: storage, temperature and use.
2. **NCMDR Standard Operating Procedures for Manufacturer, authorized representatives, importers and distributors:**

2.1 Investigations should be conducted by manufacturers, authorized representatives, importers and distributors under MDS-Surveillance & Biometrics Department supervision and control.

2.2 Manufacturers, authorized representatives, importers and distributors are required mandatorily to show and make copies of any documents or procedures that is necessary for the investigation of adverse events, this includes: service reports, evaluation reports, communication letters, complaint handling procedures, statistical information, sketches, photographs or copies of portions of operating manuals and MD tracking records.

2.3 Manufacturers, authorized representatives, importers and distributors must report to NCMDR the associated medical device subjected to an adverse events within the following interval time:

- Adverse events that result in unanticipated death or unanticipated serious injury or represent a serious public health threat must be reported immediately by the manufacturer.
- All other reportable events must be reported as soon as possible by the manufacturer, but not later than 30-elapsed calendar days following the date of awareness of the event.

2.4 Manufacturers, authorized representatives, importers and distributors are legally required to submit all recalls that related to their medical devices online through National Center for Medical Devices Reporting (NCMDR) website: [http://ncmdr.sfda.gov.sa](http://ncmdr.sfda.gov.sa)

2.5 Manufacturers, authorized representatives, importers and distributors should register in the NCMDR system in order to submitting any recall; this step will save time for next recalls submission in order not to re-enter personal information.

2.6 After submission of a recall; an acknowledge of receipt with a confirmation code will be sent to the reporter through supplied electronic mail according to “Personal Information” in the submitted recall form.
2.7 The reporter will be able to track the report status after login.

2.8 NCMDR staff will contact the reporter after recall report submission to verify the data supplied.

2.9 NCMDR staff is authorized to ask for any official documentation or material that prove the non-sale in Saudi Arabia market or that all corrective actions were undertaken as instructed by the manufacturer.

2.10 NCMDR staff will issue recommendations about the recall, and if it requires; compliance & enforcement department intervention, they will carry on any recommended action/s. For example, recommendations may include that NCMDR requests Manufacturers, authorized representatives, importers and distributors to initiate a voluntary recall.

2.11 Recommendations may have a request for voluntary recall.

2.12 Report will be closed and documented in NCMDR after recommendations were issued.

2.13 A notification letter (e-mail) with the output of the recommendations will be sent to the reporter through supplied electronic mail according to “Personal Information” in the submitted form.

2.14 Recalls will be published in the National Center for Medical Devices Reporting (NCMDR) website: http://ncmdr.sfda.gov.sa

2.15 In case of invalid recall; recall will be documented in NCMDR.

2.16 In case of false misleading recalls; recalls will be documented in NCMDR and Compliance and Enforcement Department will issue the proper enforcement and fines against the misleader reporter.

2.17 In case of serious recalls, reports will be disseminated to Safety Alert Dissemination System (SADS) and National Competent Authority Report (NCAR).
2.18 For reporting criteria, refer to Guideline: *Adverse Event Reporting Guidance for medical devices manufactures, authorized representatives, importers and distributors.* *(Appendix A)*

3-Registration On NCMDR

All Manufacturer, authorized representatives and distributors must first register

![Registration Form](image)

*Figure. 2*

in order to enter device recalls & adverse events through [www.ncmdr.gov.sa](http://www.ncmdr.gov.sa) home page. They can register by clicking on “Not registered? Click here to register” link on the public home page. All fields marked with a red asterisk (*) are required.
Registration

If you are a medical-devices supplier, please complete the form below. Registering allows you greater access to enter Adverse Events Reports and Devices recalls and to track the status of the investigation.

* indicates required fields

- Email
- Confirm Email
- Password

Must be at least 8 characters long and contain at least 3 of the following:

- Lowercase letter
- Uppercase letter
- Number
- Special Character (such as !, $, %, &)

- Confirm Password
- First Name
- Last Name
- Title
- Organization Name
- Department
- Street Address 1
- Street Address 2
- City
- State/Province
- Postal Code
- Phone
- Fax
- Website URL

Submit

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(Figure. 3)-Registration
### 3.1 Registration form Fields description

<table>
<thead>
<tr>
<th>Field Name</th>
<th>Required</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Email</td>
<td>Required</td>
<td>Your email address. This will also be used as your user name to login.</td>
</tr>
<tr>
<td>Confirm Email</td>
<td>Required</td>
<td>Retype your email to ensure there are no errors.</td>
</tr>
<tr>
<td>Password</td>
<td>Required</td>
<td>For security reasons, your password must match the complexity described below the input box</td>
</tr>
<tr>
<td>Confirm Password</td>
<td>Required</td>
<td>Retype your password</td>
</tr>
<tr>
<td>First Name</td>
<td>Required</td>
<td>Your first name or given name</td>
</tr>
<tr>
<td>Last Name</td>
<td>Required</td>
<td>Your last name or family name</td>
</tr>
<tr>
<td>Title</td>
<td>Required</td>
<td>Your title within your organization</td>
</tr>
<tr>
<td>Organization Name</td>
<td>Required</td>
<td>The name of your organization</td>
</tr>
<tr>
<td>Department</td>
<td>Optional</td>
<td>Name of your department</td>
</tr>
<tr>
<td>Street Address 1</td>
<td>Required</td>
<td>Organization mailing street address</td>
</tr>
<tr>
<td>Street Address 2</td>
<td>Optional</td>
<td>Second street address if needed</td>
</tr>
<tr>
<td>City</td>
<td>Required</td>
<td>Organization's city</td>
</tr>
<tr>
<td>State/Province</td>
<td>Optional</td>
<td>Organization's state or province</td>
</tr>
<tr>
<td>Postal Code</td>
<td>Required</td>
<td>Organization's mailing address postal code</td>
</tr>
<tr>
<td>Phone</td>
<td>Required</td>
<td>Your phone number</td>
</tr>
</tbody>
</table>
After all the required fields have been completed, click on the “Submit” button. Please remember your user name and password. Although, your account has been created, you cannot access the site until the SFDA Administrator reviews your information and activates your account.

3.2 Logging In

All Manufacturers, authorized representatives, importers and distributors must login to view existing Device Recalls, enter new Device Recalls and adverse events. To log in, click the “Log In” link on the top menu bar.

On the Log in page, enter your email address (and your password) you were used to register and your password, click on “Log In”. If you cannot remember your password forgotten, click on “Forgot your Password?” link and follow the instructions to reset your password.

Manufacturers, authorized representatives, importers and distributors are required to log in prior to submitting Adverse events. Logging in prior to entering a Report ensures that your identifying information (e.g., e-mail address, name, organization) is automatically entered.

3.3 Log Out

To log out, simply click on “Log Out” on the top menu bar.

3.4 Home Page

When a medical-device manufacturer, authorized representatives, importers and distributors user successfully logs in, the first page you see is the Home page(Figure.2). This page will display all entered Medical Device Recalls and Adverse Events currently undergoing SFDA investigation. To view an existing Recall or Adverse Events, simply click on the appropriate row.
4. Entering Device Recalls process by Medical-Device Manufacturer, Authorized representatives, and Distributors

To enter a new Device Recall, Manufacturer, authorized representatives, and distributors must first login. Once logged in, they can click on the “Device Recall” tab on the top menu bar.

The Device Recall entry page is divided into two sections (Figure.4). The first section contains your personal information which is pre-populated with information in your profile. You can make any changes you may wish. All fields marked with a red asterisks (*) are required.

(Figure.4): Home Page
(Figure 5): Device Recall – Personal Information

<table>
<thead>
<tr>
<th>Field Name</th>
<th>Required</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Optional</td>
<td>Your title within your organization</td>
</tr>
<tr>
<td>First Name</td>
<td>Required</td>
<td>First name or given name</td>
</tr>
<tr>
<td>Last Name</td>
<td>Required</td>
<td>Last name or family name</td>
</tr>
<tr>
<td>Organization</td>
<td>Required</td>
<td>Name of your organization or company</td>
</tr>
<tr>
<td>Department</td>
<td>Optional</td>
<td>Your department within your organization</td>
</tr>
<tr>
<td>Address</td>
<td>Required</td>
<td>The address of your organization or company.</td>
</tr>
<tr>
<td>City</td>
<td>Required</td>
<td>The city where your organization is located</td>
</tr>
<tr>
<td>State or Province</td>
<td>Optional</td>
<td>State or province where your organization is located</td>
</tr>
<tr>
<td><strong>Postal Code</strong></td>
<td><strong>Required</strong></td>
<td>Postal code of your organization location</td>
</tr>
<tr>
<td>----------------</td>
<td>-------------</td>
<td>--------------------------------------------</td>
</tr>
<tr>
<td><strong>Phone</strong></td>
<td><strong>Required</strong></td>
<td>You phone number including extension if necessary</td>
</tr>
<tr>
<td><strong>Fax</strong></td>
<td><strong>Optional</strong></td>
<td>Fax number</td>
</tr>
<tr>
<td><strong>Email</strong></td>
<td><strong>Required</strong></td>
<td>Your email address</td>
</tr>
<tr>
<td><strong>Website URL</strong></td>
<td><strong>Optional</strong></td>
<td>The web site of your organization</td>
</tr>
</tbody>
</table>

### Devices Information

Please be as specific as possible in identifying the devices involved. Please add any other information that might be helpful, and omit items that are not known or that appear to be irrelevant to this particular event.

- **Devices Name:**
- **Devices Type:**
- **Identifier:**
- **Manufacturer:**
- **Distributor:**
- **Event:**

**Action Needed:**

**Suggested Distribution:**

- Cardiology/Cardiac Catheterization Lab
- Clinical/Biomedical Engineering
- Clinical Laboratory/Pathology
- Critical Care
- CSR/Materials Management

Submit To SFDA

*Figure.*
The second section (Figure 7) is where you can enter information about the affected devices. Please enter all required information as completely as possible. All fields marked with a red asterisk (*) are required.

<table>
<thead>
<tr>
<th>Field Name</th>
<th>Required</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Name</td>
<td>Required</td>
<td>The model name of the device</td>
</tr>
<tr>
<td>Device Type</td>
<td>Required</td>
<td>The device type. Ex.: Amnioscopes</td>
</tr>
<tr>
<td>Identifier</td>
<td>Required</td>
<td>Serial number range, lot number, etc…</td>
</tr>
</tbody>
</table>
After all the relevant information is completed, click on the “Submit to SFDA” button to save the changes and submit the recall to the SFDA.

5. Viewing Existing Device Recalls

Manufacturers, authorized representatives, importers and distributors can view existing Adverse Events or Recalls that they submitted by clicking on the appropriate row on their Home Page. Although, no fields can be modified, only can add additional information that is appended to the report.
6. Entering an Adverse Event

Device reporting can be entered by healthcare providers, manufacturers, authorized representatives, importers, distributors and public. To enter a new Device Report as, manufacturers, authorized representatives and distributors, you must first login. Once logged in, Manufacturers, authorized representatives, importers and distributors can click on the Device report tab on the top menu bar. The Device Report entry page is divided into two sections. The first section contains your personal information which is pre-populated with information in your profile. You can make any changes you may wish. All fields marked with a red asterisks (*) are required.

6.1 Device Information

The Device Information section (Figure 8) provides NCMDR information about the device that is involved in the adverse event. All fields should be entered as completely as possible. All fields marked with a red asterisks (*) are required.

<table>
<thead>
<tr>
<th>Devices Information</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Please be as specific as possible in identifying the device involved. Please add any other information that might be helpful, and omit items that are not known or that appear to be irrelevant to this particular problem.</td>
<td></td>
</tr>
<tr>
<td>Type(s) of device(s) involved:</td>
<td>*</td>
</tr>
<tr>
<td>Manufacturer:</td>
<td>*</td>
</tr>
<tr>
<td>Local Supplier/Distributor:</td>
<td></td>
</tr>
<tr>
<td>Model:</td>
<td>*</td>
</tr>
<tr>
<td>Serial/Lot No.:</td>
<td>*</td>
</tr>
<tr>
<td>Expiration/Used Before Date:</td>
<td></td>
</tr>
<tr>
<td>How long in use:</td>
<td></td>
</tr>
<tr>
<td>Condition:</td>
<td></td>
</tr>
<tr>
<td>Date event occurred: (N/D/yyyy) CE</td>
<td></td>
</tr>
<tr>
<td>Date last inspected or serviced: (M/D/yyyy) CE</td>
<td></td>
</tr>
<tr>
<td>Where there other devices involved?:</td>
<td>Yes No</td>
</tr>
<tr>
<td>If yes, please describe:</td>
<td></td>
</tr>
<tr>
<td>Are the devices available for inspection?:</td>
<td>Yes No</td>
</tr>
<tr>
<td>If a single-use device were involved, were they reprocessed at any time before the incident?:</td>
<td>Yes No</td>
</tr>
<tr>
<td>Are other units of the same model similarly affected?:</td>
<td>Yes No</td>
</tr>
</tbody>
</table>

(Figure 8): Device Recall Information
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Required</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type(s) of device(s) involved</td>
<td>Required</td>
<td>The type of devices that were involved in the event.</td>
</tr>
<tr>
<td>Manufacture</td>
<td>Required</td>
<td>The manufacture of the device.</td>
</tr>
<tr>
<td>Local Supplier/Distributor</td>
<td>Required</td>
<td>The local supplier or distributor of the device</td>
</tr>
<tr>
<td>Serial/Lot No</td>
<td>Required</td>
<td>The serial number or lot number of the device</td>
</tr>
<tr>
<td>Expiration/Used Before Date</td>
<td>Optional</td>
<td>If the device is a single-use device, enter the expiration or Use Before Date</td>
</tr>
<tr>
<td>How long in use</td>
<td>Optional</td>
<td>Enter how long the device was in use. Ex.: 4 years 3 months</td>
</tr>
<tr>
<td>Condition</td>
<td>Optional</td>
<td>The condition of the device at the time of the incident. Ex.: Brand new</td>
</tr>
<tr>
<td>Date Adverse Event occurred</td>
<td>Required</td>
<td>The date the Adverse Event occurred (this should be enter in Common Era year)</td>
</tr>
<tr>
<td>Date last inspected or serviced</td>
<td>Optional</td>
<td>Date the device was last inspected or serviced</td>
</tr>
<tr>
<td>Where other devices involved?</td>
<td>Optional</td>
<td>If other devices were involved in the incident, check Yes and enter the devices in the box below. If there were no other devices involved, check No.</td>
</tr>
<tr>
<td>If yes, please describe</td>
<td>Optional</td>
<td>If there were other devices involved in the Adverse Event, enter the devices here.</td>
</tr>
<tr>
<td>Is the device</td>
<td>Optional</td>
<td>Check Yes if SFDA is able to inspect the</td>
</tr>
</tbody>
</table>
available for inspection? device. Check No, if the device is unavailable for inspection.

If a single-use device was involved, …

<table>
<thead>
<tr>
<th>Optional If the device is a single-use device, indicate if the device was reprocessed.</th>
</tr>
</thead>
</table>

Are other units of the same model similarly affected?

<table>
<thead>
<tr>
<th>Optional Indicate if you are experiencing similar Adverse Event with other units of the same model.</th>
</tr>
</thead>
</table>

6.2 Adverse Event Description

Please use the text box (Figure 9) to describe the hazard or adverse event in detail. Include how it was discovered, any action you took, and the response of any Manufacturers, authorized representatives, importers and distributors. Please also mail or fax any related correspondence when possible. Sketches, photographs, or copies of portions of operating manuals are often helpful in describing the Adverse Event, especially if the affected device is not available for examination at SFDA. Retain all disposable accessories involved in an incident. Please do not send any devices to SFDA until requested. All fields marked with a red asterisks (*) are required.
Adverse Event Description

**Outcome of the adverse event:**
- [ ] Death
- [ ] Injury
- [ ] Near Miss
- [ ] Other
- If other: __________

Please use the following text box to describe the hazard or problem in detail. Include how it was discovered, any action you took, and the response of any suppliers or manufacturers. Please also mail or fax any related correspondence when possible. Sketches, photographs, or copies of portions of operating manuals are often helpful in describing the problem, especially if the affected devices are not available for examination at SFDA. Retain all disposable accessories involved in an incident. Please do not send any devices to SFDA until requested.

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(Figure.9): Adverse Event Description

<table>
<thead>
<tr>
<th>Field Name</th>
<th>Required</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome of the</td>
<td>Optional</td>
<td>If the Adverse Event resulted in death, injury, or near miss, check the appropriate button. Otherwise, please click Other and briefly describe the outcome in the box immediately below.</td>
</tr>
<tr>
<td>Adverse Event Details</td>
<td>Required</td>
<td>Please enter details of the Adverse Event. The more relevant details you provide, the quicker SFDA can assess the Adverse Event.</td>
</tr>
</tbody>
</table>
Appendix A

Adverse Event Reporting

Criteria for NCMDR

( Guidance for Manufacturers & Authorized Representatives, Importers, Distributors)
Reporting Criteria

The objective of the adverse event reporting and subsequent evaluations is to improve protection of the health and safety of patients, users and others by disseminating information which may reduce the likelihood of, or prevent repetition of adverse events, or alleviate consequences of such repetition. Thus, This document will explain what should be reported to SFDA.

The main criteria for submitting adverse event report to NCMDR are:

1. An Event has Occurred

The manufacturer becomes aware of information regarding an event which has occurred with its device.

This also includes situations where testing performed on the device, examination of the information supplied with the device or any scientific information which may indicate that some factors could lead or has led to an event.

Typical events are:

a) A malfunction or deterioration in the characteristics or performance.

A malfunction or deterioration should be understood as a failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions.

The intended purpose means the use for which the device is intended according to the data supplied by the manufacturer on the labeling, in the instructions and/or in promotional materials.

b) An inadequate design or manufacture.

This would include cases where the design or manufacturing of a device is found deficient.
c) An inaccuracy in labeling, instructions for use and/or promotional materials. Inaccuracies include omissions and deficiencies.

Omissions do not include the absence of information that should generally be known by the intended users.

d) A significant public health concern.

This can include an event that is of significant and unexpected nature such that it becomes alarming as a potential public health hazard, e.g. human immunodeficiency virus (HIV) or Creutzfeldt-Jacob Disease (CJD).

e) Use Error

**Reporting of Use Error**

As with all reported device complaints, all potential use error events and potential abnormal use events should be evaluated by the manufacturer. The evaluation is governed by risk management, usability engineering, design validation, and corrective and preventive action processes. Results should be available, upon request, to regulatory authorities and conformity assessment bodies.

- **Use Error Resulting in Death or Serious Injury/ Serious Public Health Concern**

  Use error related to medical devices, which did result in death or serious injury or serious public health concern, should be reported to the SFDA.

- **Use errors becoming reportable**

  Use errors become reportable to the SFDA when you:

  - notes a change in trend (usually an increase in frequency), or a change in pattern of an issue that can potentially lead to death or serious injury or public health concern.; or
  - initiates corrective action to prevent death or serious injury or serious public health concern.
f) Any other information that becomes available.

This can include results of testing performed by the manufacturer on its products, or by the
user prior to being used on the patient, or by other parties. This can also include
information from the literature, other scientific documentation or increase in trend.

2. An Event Leads to One of the Following Outcomes:

- Death of a Patient, User or Other Person.
- Serious Injury of a Patient, User or Other Person.

Serious injury (also known as serious deterioration in state of health) is either:

- Life threatening illness or injury.
- Permanent impairment of a body function or permanent damage to a body
  structure.
- A condition necessitating medical or surgical intervention to prevent permanent
  impairment of a body function or permanent damage to a body structure.

The interpretation of the term "serious" is not easy, and should be made in consultation
with a medical practitioner when appropriate.

The term “permanent” means irreversible impairment or damage to a body structure or
function, excluding minor impairment or damage.

Medical intervention is not in itself a serious injury. It is the reason that motivated the
medical intervention that should be used to assess the report ability of an event.

- No Death or Serious Injury Occurred but the Event Might Lead to Death or
  Serious Injury of a Patient, User or Other Person if the Event Recurs.

All events do not lead to a death or serious injury. The non-occurrence of such a result
might have been due to circumstances or to the timely intervention of health care
personnel.
The event is considered “adverse” if in the case of reoccurrence, it could lead to death or serious injury.

This applies also if the examination of the device or a deficiency in the information supplied with the device, or any information associated with the device, indicates some factor which could lead to an event involving death or serious injury.

Include relevant information that might impact the understanding or evaluation of the adverse event AND that is not included elsewhere in this report.

3. The Manufacturer’s Device is Associated with the Event

In assessing the link between the device and the event, the manufacturer should take into account:

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

This judgment may be difficult when there are multiple devices and drugs involved. In complex situations, it should be assumed that the device was associated with the event.

Exemption Rules

Whenever exemption rules are met, the adverse event does not need to be reported to the SFDA.

1. Deficiency of a Device Found by the User prior to patient use

Deficiencies of devices that would always be detected by the user and where no serious injury has occurred do not need to be reported.

Based on the information stated, these are examples of non-reportable adverse events:
* User performs an inflation test prior to inserting the balloon catheter in the patient as required in the instructions for use accompanying the device. A malfunction on inflation is detected. Another balloon is used. Patient is not injured.

* Packaging of a sterile single use device is labeled with the caution ‘do not use if package is opened or damaged’ but damage to the packaging was obvious and discovered, and the device was not used.”

2. **Adverse Event Caused by Patient Conditions**

Due to a patient’s condition, the event does not need to be reported. These conditions could be preexisting or occurring during device use.

Examples of non-reportable adverse events:
* Revision of an orthopedic implant due to loosening caused by the patient developing osteoporosis.
* A patient died after dialysis treatment. The patient had end-stage-renal disease and died of renal failure.
* A death of a patient that is unrelated to any implanted device or device used to treat the patient.

3. **Service Life or shelf life of the Medical Device**

When the only cause for the adverse event was that the device exceeded its service life or shelf life as specified by the manufacturer and the failure mode is not unusual, the adverse event does not need to be reported.

The service life or shelf life must be specified by the device manufacturer in the medical device labeling or instructions for use. Service life or shelf life is defined as : the time or usage that a device is intended to remain functional after it is manufactured, placed into use, maintained as specified.

Examples of non-reportable adverse events:
*Loss of sensing after a pacemaker has reached its expected end of life as indicated in the instructions for use. Elective replacement indicator has shown up in due time according to device specification. Surgical explanation of pacemaker required.  
* Surgical glove was used after expiry date. User was exposed to infected blood due to glove failure.

4. **Protection against a fault function Correctly**
Adverse events which did not lead to serious injury or death, because a design feature protected against a malfunction becoming a hazard do not need to be reported. The protection against malfunction used needs to comply with relevant standards or documented design inputs for that type of device and take due account of technology and practice in existence. The risk has to be reduced to an acceptable level.

Examples of non-reportable adverse events:
* During radiation treatment, the automatic exposure control is engaged. Treatment stops. In accordance with the relevant standards the actual dose is displayed. Although patient receives less than optimal dose, patient is not exposed to excess radiation.

5. **Negligible Likelihood of Occurrence of Death or Serious Injury**
Adverse events which could lead, but have not yet led, to death or serious injury, but have a negligible likelihood of causing death or serious injury, and which have been established and documented as acceptable after risk assessment do not need to be reported.

Examples of non-reportable adverse events:
* Manufacturer of pacemaker released on the market identified a software bug and determined that the likelihood of occurrence of a serious injury with a particular setting is negligible. No patients experienced adverse health effects.

6. **Expected and Foreseeable Side Effects.**
Expected and foreseeable side effects which meet all the following criteria:

- clearly identified in the manufacturer's labeling;
- clinically well known as being foreseeable and having a certain qualitative and quantitative predictability when the device is used and performs as intended;
- documented in the device master record, with an appropriate risk assessment, prior to the occurrence of the adverse event; and
- clinically acceptable in terms of the patient benefit

are ordinarily not reportable.

Examples of non-reportable adverse events:

- A patient who is known to have claustrophobia experiences severe anxiety in the confined space of a MRI machine which subsequently led to the patient being injured.
- A patient receives a second-degree burn during the use in an emergency of an external defibrillator. Risk assessment documents that such a burn has been accepted in view of potential patient benefit and is warned in the instructions for use. The frequency of burns is occurring within range specified in the device master record.

7. Adverse Events Described in an Advisory Notice.

Adverse events that occur after the manufacturer has issued an advisory notice need not be reported individually if they are specified in the notice and if they have the same root cause for the products identified in that notice. Advisory notices include removals from the market, corrective actions, and product recalls. The manufacturer should provide a summary report, the content and frequency of which should be agreed with the relevant SFDA.

Example of non-reportable adverse events

* Manufacturer issued an advisory notice and recall of a coronary stent that migrated due to inadequate inflation of an attached balloon mechanism. Subsequent examples of stent migration were summarized in quarterly reports concerning the recall action and individual adverse events did not have to be reported.

8. Reporting Exemptions Granted by a SFDA.
Upon request by the Manufacturers, authorized representatives, importers and distributors and agreement by an SFDA, common and well-documented events may be:

- Exempted from reporting or
- changed to periodic or summary reporting.