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- About the person filling out this form
   - Name:
   - Number:
   - Email Address:

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