Ethiopian Food and Drug Authority (EFDA)
Medical Devices Adverse Event Reporting (MDAER) form for Healthcare professionals and Users

MDAER is one of the post market surveillance tools that EFDA uses to monitor device performance, detect potential device-related safety issues, and contribute to risk- benefit assessments of these products.

Patient/ User (Name or Initial) :	Age (DOB)	sex	Weight	Height

Suspected Medical Device Details:

Generic and Brand Names:	Model:	Serial No.	Lot/Batch No.	UDI-DI/UDI-PI	code/catalogue No:

Manufacturer:		Mfg. Date		Device supplier :	
Address:				Address:	
contact:		Exp. Date		contact:	

Description of the Adverse Event: *Was the AE serious?* ☐ YES ☐ NO If yes select Reason for Seriousness:

☐ *Patient death occurred* ☐ *Serious injury to patient* ☐ *No death/ serious injury to patient, but death/ serious injury might occur if AE happens again*

What kind of problem was it? (Check all that apply):

☐ *Noticed a problem with the quality (performance) of the product*

☐ *Had problems after switching from one product maker to another maker*

Other (specify) :

☐ *Used a product incorrectly which could have or led to a problem*

☐ *Were hurt or had a bad side effect (including new or worsening symptoms)*

Date and time the problem occurred:

Tell us what happened and how it happened (Include as many details as possible). Please include the clinical/analytical procedure during which the observation was made.

How repetitive is the AE: Number of devices with the problem (% of devices involved:)

Was someone operating the medical device when the problem occurred: ☐ YES ☐ NO

If yes, who was operating it? Other:

☐ The person who had the problem (user)

☐ HC professional (such as a doctor, nurse, or lab tech.)

For implanted medical devices ONLY (such as pacemakers, IUDs, catheters, orthopaedics etc.)

Date of Implantation:

Date of explanation (if applicable)

Place/facility where the implantation was done:

Relevant medical conditions related with implants:

Reported By, Name:	Profession:	Email address :	Telephone:

Address: Regions/City	Zone	Sub city	Woreda

Name of Health Institutions:	Date

Reset Submit

What is Medical Device?

Medical device means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related articles and their accessories, which are intended by the manufacturer to be used, alone or in combination, for medical purpose and includes device intended for related medical use and control of contraception.

In vitro medical device (***IVD***) means a device intended by the manufacturer for the in vitro examination of specimens derived from the human body to provide information for diagnostic, monitoring or compatibility purposes

What To Report?

Adverse events

- *Death of the patient, end-user or any other person occurred (e.g. Balloon catheter failed to deflate and patient death resulted)*
- *Serious deterioration in health of the patient, end-user or any other person occurred , like:*

- *Life threatening*
- *Permanent damage to a body structure*
- *Permanent impairment to a body function*
- *Extended Hospitalization*
- *Condition which necessitates medical or surgical intervention.*

- *No death/ serious injury to patient, but death/ serious injury might occur if AE happens again*

(e.g. Failure code in infusion pump caused pump to stop infusion; nurse, who was present, rectified device malfunction)

For IVDs:

- *A false negative result*
- *A false positive result*
- *Non-reproducible results*
- *High or low readings, high or low-test results*
- *Failure to calibrate*
- *Increased rate of invalid or unreturnable test results*
- *Obviously incorrect, inadequate or imprecise result or readings*
- *Unable to obtain reading*

Quality Defects/ Malfunctions:

- *damaged, defective or suspect tampered Packaging.*
- *Labelling– insufficient instructions for use, illegible*
- *device doesn't collect/transfer specimen*
- *Mechanical – misalignment, jam, Liquid – leak, splash*
- *unable to charge, power loss or fluctuation*
- *Data – capture, display, or storage affecting product functionality*
- *Software – network, program, algorithm, or security affecting product functionality*
- *Environmental – noise, temperature, humidity/ moisture, fungal/bacterial growth, or dust affecting product functionality*
- *Falsified/counterfeit medical Devices that deliberately/fraudulently misrepresent their identity, composition or source.*

⇒ **Note:** *this is not an exhaustive list of feedback that should be reported, If you have experienced any incidents related to a medical device do not hesitate to report them.*

The information in this report is confidential and totally protected including both the Patient and Reporter identity.

EFDA
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ETHIOPIAN FOOD & DRUG AUTHORITY

How to Report:

Toll free # **8482**
National Medical Device Vigilance Centre: **medsafety@efda.gov.et**
e-reporting form on EFDA website: www.efda.gov.et
Telephone: 0115-523142 P.O.Box 5681

⇒ Fill page 1 of this form and submit it to EFDA Medical Device Manufacturer Inspection and Enforcement LEO.

What should you do with the device?

Please keep the device and its associated packaging until you are contacted by the EFDA Medical Device Vigilance Centers.