MEDICAL DEVICES AND IN VITRO DIAGNOSTICS ADVERSE EVENT/INCIDENT REPORTING FORM FOR CONSUMERS AND HEALTHCARE FACILITIES

For TMDA internal use only	***Report Number:***	***Date received:*** _____ /_____/_____

1. DEVICE DETAILS

Full name of the Medical Devices or In Vitro Diagnostic Brand name: Common name:	Size (*if applicable):*
Manufacturing date: _____/_____/_____	Serial number:
Expiry date: _____/_____/_____	Batch number/lot number:
Manufacturer's name and physical address:	
Source of device: *Please (√) where required,* ☐ Hospital ☐ Pharmacy/Medical Device outlet ☐ Diagnostic Centre ☐ Others	Name of the supplier and physical address (if known):
Status of the device: Please (√) where required. ☐ New device ☐ Re-serviced/refurbished	
How long the device has been in use: ☐ Less than six (6) months ☐ Less than one (1) year ☐ 1-5 years ☐ Others, Explain*:*	

2. INCIDENT DETAILS

Onset date of incident: _____/____ /_____

Type of incident *(device related): Please (√) where required.*

☐ Inadequate design ☐ Inaccurate labeling/instruction for use ☐ Malfunction ☐ Deterioration

☐ Other, please give details:

Incident narrative description (explain what went wrong with the device):

Number of devices involved:

3. EVENT DETAILS

Onset date of event: _____/____ /_____

Type of event *(user related): Please (√) where require.*

☐ Death ☐ Life threatening ☐ Malfunction ☐ Caused persistent disability or incapability

☐ Required or prolonged hospitalization ☐ Other, please give details: Event narrative description (explain what went wrong with the device):
Number of users involved:
4. USER/EQUIPMENT OPERATOR DETAILS
User/Operator at the time of event/ incident. Please (√) where required: ☐ Healthcare Providers ☐ Maintenance Engineer ☐ Other, Mention
Measures taken by the user/operator:
Outcome of the measures taken: (if applicable).
Have you informed the supplier? *Please (√) where required:* ☐ Yes Date: ____ /___ /_____ ☐ No

5. PARTICULARS OF THE REPORTER/ HEALTH CARE PROVIDER	
Name or Initials:	☐ Medical practitioner ☐ Other
Physical address (facility):	
District/Region/City:	Email:
Telephone/Mobile phone:	Date of report: _____ / ____ / _____
Current location of the device:	

Thank you for your cooperation	***Submission of an adverse event report does not discredit the competence of the reporter***

Send to:

The Director General,
Tanzania Medicines and Medical Devices Authority (TMDA),
P.O.Box 1253,
Dodoma, Tanzania
Tel: +255 (26) 2961989/2061990
Email: info@tmda.go.tz
Website: www.tmda.go.tz
Toll free number: 0800110084