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

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

1. DEVICE DETAILS	
Full name (Brand and Common):	Size (*if applicable):*
Manufacturing date: ____/___/_____	Serial number:
Expiry date: ____/___/_____	Batch number/lot number:
Manufacturer name and address:	
Source of device. *Please (√) where required:* ☐ Hospital ☐ Store ☐ Other	Name of the supplier and address:
Status of the device. Please (√) where required: ☐ New device ☐ Re-serviced/refurbished	
Current location of the device:	

2. EVENT/INCIDENT DETAILS

Onset date of event/incident: ____/___/_____

Type of Event (user related): *Please (√) where required:*

☐ Death ☐ Life threatening ☐ Caused persistent disability or incapacity ☐ Required or prolonged hospitalization ☐ Other, please give details:

Event description narrative (explain what went wrong):

Number of patients involved:

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

☐ Inadequate design ☐ Inaccurate labeling/instruction for use ☐ Malfunction ☐ Deterioration ☐ Other, please give details:

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

Number of medical devices involved:

How long the device has been in use: ☐ Less than six (6) months ☐ Less than one (1) year ☐ 1-5 years ☐ Others, *Explain:*

Operator at the time of event/ incident. Please (√) where required: ☐ Medical practitioner ☐ Other, *Please give details:*
Measures taken by the user:
Have you informed the supplier? *Please (√) where required:* ☐ Yes Date: ☐ No

3. REPORTER DETAILS	
Name of Reporter or Initials:	
Address:	
District/Region/City:	Email:
Telephone/Mobile phone:	Date of report: ____/___/_____

Send to:

The Director General,
Tanzania Medicines and Medical Devices Authority (TMDA),
P.O.Box 1253,
Dodoma, Tanzania

OR

P.O.Box 77150,
Dar Es Salaam, Tanzania
Tel: +255 22 2450512 / 24507551
Email: info@tmda.go.tz
Website: www.tmda.go.tz
Toll free number: 0800110084