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 (Brand and Common):	Size (*if applicable):*
Manufacturing date: _____/_____/_____	Serial number:
Expiry date: _____/_____/_____	Batch number/lot number:
Manufacturer's name and address:	
Source of device. *Please (√) where required:* ☐ Hospital ☐ Pharmacy/Medical Device outlet ☐ Diagnostic Centre ☐ Others	Name of the supplier and address:
Status of the device. Please (√) where required: ☐ New device ☐ Re-serviced/refurbished	
Current location of the device (Facility Name):	

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. PARTICULARS OF THE REPORTER/HEALTH CARE PROVIDER	
Name or Initials:	Profession:
Address of the facility/Centre:	
District/Region/City:	Email:
Telephone/Mobile phone:	Date of report: _____ / ____ / _____

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

Send to:

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