TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

TMDA
Tanzania Medicines & Medical Devices Authority

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

TMDA Internal Use Only	
Report Number:	*Date received:*

1. Device details	
Brand name:	*Catalogue:*
	Model number:
Manufacturing date:	*Serial number:*
Expiry date:	*Batch number/lot number:*
Is the Device CE marked? Yes No	*Instructions for use provided(where possible please attach a copy)* Yes No
Manufacturer name :	*Address:*
Name of supplier	*Address:*
	Telephone:
Current location of the device:	

2. Event/Incident details	*Date of incident:*
Type of incident(*patient related*): Death ☐ Serious ☐ Distress ☐ minor ☐ None other	
Type of incident(device related): Inadequate design inaccurate labeling malfunction deterioration other	
Event/Incident description narrative (explain what went wrong with the product)	

Measures taken by the user			
Number of patients involved:			
Operator at the time of the event/incident (please choose): (Please cross where required)	*Laboratory personnel*	*Other Health care personnel*	*Other*
Have you informed the supplier /manufacturer?	☐ *Yes* ☐ No	*Date:*	

3.Reporter details	
Name of Person/facility:	
Postal address:	*Street Name:*
City:	*District/Region:*
Telephone/Mobile phone:	*Fax:*
Name of contact person:	
Email of contact person:	
Date of report:	
Signature:	

Send to:

The Director General,

Tanzania Medicines and Medical Devices Authority (TMDA),
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