ASSESSMENT REPORT FORMAT FOR ADVERSE EVENTS/ INCIDENTS FOR MEDICAL DEVICES AND IN VITRO DIAGNOSTICS

(This assessment report should be written in clear unambiguous language and typed with "Book Old Style" font size 11. The format of tables must not be changed)

Name and Address of the reporter	
TFDA report number	
Device registration number	
Facility/Supplier/Manufacturer name and address	
Date received TFDA	
Initial/ Follow up/Final reports	
Device name and class	
Date Event reported	
Event description *(write as presented by the reporter)*	
TFDA Assessor's Causality assessment of the event (Possible, Unrelated, Unassesible)	
Name of Assessor and Signature	
Date of assessment	
MMDA's Comments	
MMDA's name and signature	
Review date	