MEDICAL DEVICES AND IN VITRO DIAGNOSTICS ADVERSE EVENT/INCIDENT REPORTING FORM FOR IMPORTERS/SUPPLIERS

TMDA Internal Use Only	
Report Number:	*Date received: _____ / ____ / _____*
1. Contact details of the reporting company	
Name of company:	*Importer/supplier/distributor (Please specify):*
Postal address:	*Street Name:*
City:	*District/Region:*
Tel: *Mob:* *Fax:*	
Name and position of contact person:	
Email of contact person:	
2. Product details	
Product /commercial /brand name:	
Catalogue/Model number:	*Serial /batch /lot number:*
Manufacturing date: _____ /____ / _____	*Expiry date: _____ / ____ / _____*
Name of associated devices/accessories:	*Instructions for use version number:*
Name of Marketing Authorization Holder (MAH):	*Postal address:*
Manufacturer name and address:	
3. Event/problem details	
Event/problem description narrative (explain what went wrong with the product and the observed orlikely/probable consequences):	
Date: ____ / ____ / _____ *Place of the event/problem:*	
Number of cases involved:	*Are cases from different units involved?* ☐ *Yes* ☐ *No*
Operator at the time of the event/problem (Please choose):	☐ *Laboratory personnel* ☐ *Non-laboratory personnel* ☐ *other*
Has more than one customer experienced the problem with the product? ☐ *Yes* ☐ *No*	
Type of specimen used (please specify):	*Reading time observed:* *Date: _____ / ____ / _____*
Have you informed the vendor? ☐ *Yes* ☐ *No*	

What measures have been recommended?		
Have you informed the manufacturer?	☐ *Yes* ☐ *No*	*Date:*
What measures have been recommended?		
Measures taken by the Importer/supplier:		
Date of report: _____ / ____ / _____	*Signature:*	

Send to:

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