MEDICAL DEVICES AND INVITRO DIAGNOSTICS ADVERSE EVENT/INCIDENT REPORTING FORM FOR MANUFACTURERS

TMDA Internal Use Only	
Report Number:	*Date received:*
1. Administrative information	
Date of this report:	Reference number assigned by the manufacturer:
Type of report	☐ Initial report ☐ Follow-up report ☐ Combined Initial and Final report ☐ Final report
Does the incident represent a serious public health threat? ☐ Yes ☐ No	Please explain:
2. Manufacturer information.	
Name:	Postal address:
Email:	Physical address:
Phone:	Fax:
Contact person's name:	Postal address;
Email:	Physical address:
Phone:	Fax:
3.Local Representative information	
Name:	Postal address:
Phone:	Physical address
Fax:	Email:
Contact person's name:	
Phone:	Email:

5. Device details	
Brand name: Common name:	Catalogue number: Model number:
Manufacturing date:	Serial number:
Expiry date:	Lot/batch number:
Is the Device CE marked? ☐ Yes ☐ No	Instructions for use provided (*Where possible please attach copy*) ☐ Yes ☐ No
☐ New device ☐ Used/refabricated device	Duration of use:
6. Event/Incident details	
User facility report reference number (*if applicable):*	
Manufacturer's awareness date:	Date the incident occurred:
Incident description narrative:	
Number of patients involved:	Number of products involved:
Current location of the device:	
Usage of the medical device	☐ Initial use ☐ Reuse of a single use, Reuse of a reusable, ☐ Re-serviced/refurbished ☐ Problem noted prior use other (please specify):
7. Manufacturer's preliminary comments (Initial/Follow-up report)	
Manufacturer's preliminary analysis(Narrative):	
Initial corrective actions/preventive actionsimplemented by the manufacturer:	
Expected date of next report:	
8. Results of manufacturers final investigation (Final report)	
The manufacturer's device analysis results:	
Remedial action/corrective action/preventive action/ Field Safety Corrective Action:	

Action taken to prevent further risk to thepatient (Narrative):	
Time schedule for the implementation of the identified actions:	
Final comments from the manufacturer:	
Further investigations:	
Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause?	☐ Yes No ☐
Number of similar incidents:	
If yes, state in which countries and the report reference numbers of the incidents.	
Has a similar event occurred in these regions?	☐ EAC ☐ EU

9. Conclusion

I affirm that the information given above is correct to the best of my knowledge

Name: Signature: Date:

Send to:

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