MEDICAL DEVICE COMPLAINT/ INCIDENT FORM

This form is to be used by <u>medical device user</u> from government or private institutions to complaint of medical device safety and performance issue under Medical Device Act 2012 (Act 737). This complaint must be completed and submitted to the establishment (company) and copy to Medical Device Authority (MDA).

Complainant	☐ **Government** ☐ **Private**		
Institution	☐ **Hospital** ☐ **Clinics** ☐ **Others: _____**		
A. Device Particulars			
Device name			
Brand name			
Description of medical device (as appeared on label) name			
Intended use (as appeared on label)			
Batch/ Lot/ Serial no.		Expiry date	
B. Establishment Particulars			
Name of manufacturer (if local device) / Name of authorized representative (if imported device)			
Manufacturer's / Authorized Representative's address			
Contact person			
Job title			
Telephone no.		Fax no.	
Email			
Name of distributor			
Distributor's address			
Contact person name			
Job title			
Telephone no.		Fax no.	
Email			
C. Complaint Information			
Description of complaint/ incident			
History of complaint/ incident			

Is there any injury happened?	☐ Yes ☐ No
If Yes, what is the category of incident?	☐ Serious public health threat ☐ Death ☐ Serious injury ☐ Non-serious injury
All complaints shall be reported to the establishment. Does the establishment alerted on this?	☐ Yes ☐ No

D. Complainant Information

Name			
Position/ Occupation		Department/ Unit	
Address			
Telephone no.		Fax no.	
Email			

E. Other Information

I attest that the information submitted is true and correct.

Signature : _____

Name of reporting person : _____

Date of reporting : _____ **(dd/mm/yyyy)**

Organization stamp : _____