Medical Device Adverse Event Reporting Form for Medical Device Users

MDUAE Form
Last revised
22 Jan 2020

MEDICAL DEVICE USER ADVERSE EVENT REPORTING FORM

*Fields marked with an asterisk * should be completed before submitting this form.*

I - DEVICE DETAILS *(Alternatively, submit clear photo(s) of the device label containing the mandatory device details)*	
Device Name *	
Model No. *	
Serial No.	
Lot/Batch No.	
Software version	
Date of manufacture *(dd/mm/yyyy)*	
Date of expiry *(dd/mm/yyyy)*	
Duration of use/Date of implantation *(If applicable)*	
Name of manufacturer of device	
Name of local supplier of device *	
II - DESCRIPTION OF EVENT	
Date of Adverse Event *(dd/mm/yyyy)* *	
Description of Event or Problem * *Please provide as much details as you can, including what led to the event, the chronology of events, the consequences of the event, patient outcome and any remedial action taken.*	
Operator of device at the time of the event *(please select one)*	☐ Physician ☐ Patient ☐ Others (Please specify:) ☐ None or problem noted prior to use

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Was device returned to local supplier? *(please select one)* *If possible, do not discard the device as it may be needed for device investigation.*	☐ Yes (Please specify date of return:) ☐ No (Please specify location:)
Other relevant information, if any *(e.g. patient history, laboratory data, other medical products in use at the time of event)*	
III – PATIENT INFORMATION *(this will help in identifying duplicate reporting)*	
Age of patient at time of event *(years)*	
Gender	
IV – PARTICULARS OF REPORTING PERSON	
Name (Dr / Mr / Mrs / Ms) *	
Profession / Designation	
Tel no. *	
Email Address *	
Date of this report (dd/mm/yyyy)	
Healthcare Facility Name	
Was the local supplier informed of this event? *(please select one)*	☐ Yes (Please specify date:) ☐ No
I agree to HSA sharing my name and contact information with the local supplier, to facilitate investigation of the event. *(please select one)* * ☐ Yes ☐ No	

HOW TO REPORT

Email: hsa_medical_device@hsa.gov.sg

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