2-Clinical Event Information			
Description of event or problem			
3-Healthcare Facility Information			
Name			
Address			
Tel		Fax	
E-mail			
Contact Name			
4- Device Information			
Name of Device			
UMDNS Code			
Device Classification			
Brand Name			
Model number			
Catalogue number			

Registration number			
(Serial number/ lot number / batch number)			
Date of manufacture	...../...../.....	Date of Installation	...../...../.....
Manufacturer Name			
Address			
Tel		Fax	
E-mail			
Contact Name			
Distributor/Authorized representative			

Operator of Device at Time of Event (select one)

Healthcare Professional ☐ Other Caregiver ☐ Patient ☐
Not applicable ☐

Usage of Device

1-Single use ☐
2-Reuse of Reusable ☐
3-Re-serviced/Refurbished ☐
4-Implanted ☐ Date of implantation ...../...../.....
5-Other.....

Current Location

5- Results of Manufacturer's Device Investigation
Manufacturers Device Analysis Results
Remedial Action/Corrective Action/ Preventive Action (Specify if/what action was taken for the reported specific event or for all similar type of events or products.) recall ☐ relabeling ☐ patient monitoring ☐ repair ☐ notification ☐ adjustment ☐ replace ☐ inspection ☐ other ---------- what action was taken to prevent recurrence? Clarify the timeframe for completion of various action plans.

6- Patient Information					
Age		M/F		Wt(kg)	
Corrective action taken relevant to the care of the patient					
Patient outcome					
list of other devices involved in the event					
7- Other Information					
Manufacturer aware of other similar events:					
Countries where these similar adverse events occurred:					
Additional Comments					

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