MEDICAL DEVICE CONTROL OFFICE

USER REPORTING FORM – MEDICAL DEVICE INCIDENTS

This is a voluntary report form for reporting suspected problem with a medical device that **may present a hazard**. Submission of this report does not constitute an admission by the reporter of liability for the event and its consequences. It is also not a conclusion that the device caused or contributed to the adverse event. Information of individual reporter and patient will be treated in strict confidence. For enquiries, please contact the MDCO at telephone no. 2961 8788.

MDCO Report No.
(Official Use Only)

I. DEVICE INFORMATION

1.	Device Description			
2.	Brand Name and Model			
3.	Serial No., Batch No., or Lot No.		4. MDCO Listing No. (if known)	

5. Is the device or its packaging available for inspection? ☐ Yes ☐ No

II. SUPPLIER INFORMATION

1.	Company Name			
2.	Name of Contact Person		3. Telephone No.	

4. Have you reported this problem to other parties?

☐ No ☐ Yes, please provide the name of the company, the name of the contact person, the telephone no. and the date:

Name of Company: _____ Name of Contact Person: _____

Telephone No.: _____ Date: _____

III. PROBLEM DESCRIPTION

1. Please give a brief description of the problem:

2. Consequence of the problem: ☐ Death ☐ Serious Injury ☐ Might lead to death or serious injury if recurs ☐ Nil

Please elaborate:

IV. REPORTER INFORMATION

1.	Name of the Organization			
2.	Name of the reporter		3. Position	
4.	Contact Telephone No.		5. Contact Fax. No.	
6.	E-mail Address		7. Date of Report	

V. SUBMISSION OF REPORT

1.	By Mail:	Medical Device Control Office 18/F., Wu Chung House 213 Queen's Road East, Wan Chai, HONG KONG	2. By Fax.: (852) 3157 1286 3. By E-mail: mdco_air@dh.gov.hk