Field Safety Corrective Action Closure Report form

FSCA Reference:	
Medical Device Name:	
Manufacturer:	
MDMA Authorization Numbers/ Low Risk Device Numbers	

	Actions	Comment
1	The number of all affected customers	
2	Methods of communications used	☐ Phone, ☐ Email, ☐ Visit, ☐ Registered Mail ☐ Other:
3	All affected customers notified (reached) and are acknowledged (replied)?	All notified: ☐ Yes, ☐ No: number of not notified All replied: ☐ Yes, ☐ No: number of not replied If you answer (NO), you must provide a list of the customers' names, city, contact details and communication history and whether they were not notified or not acknowledged
4	The number of all affected products	
5	The number of used/consumed products	Consumed number: , or ☐ N/A
6	The number of corrected/removed products	
7	The number of products that were not located (at healthcare facility premises)	Not located number: , or ☐ N/A
8	Specify the action done for any recovered products	☐ Destroyed, ☐ Shipped outside KSA, ☐ N/A, ☐ Other:
9	Choose which field actions were implemented (other than notifying customers)	☐ Product Removal ☐ On-site device modifications/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ None ☐ Other:

I hereby confirm that I am authorized from the company listed below, and I am aware of SFDA Safety Alerts requirements, and I have verified the information provided in this document.	
Authorized Person Name:	
Company Name	
Date:	
Signature:	