Corrective Action Implementation Plan form

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

	Requirements	Comment
1	All affected customers notified	☐ Yes ☐ No, Details:
2	Number of affected products (specify units. for example: Pieces, Box, Kits, etc.)	
3	Planned methods to be used when notifying the customers by the Field Safety Notice	☐ Phone, ☐ Email, ☐ Visit, ☐ Registered Mail ☐ Other:
4	Choose which remaining field actions to be implemented (other than notifying customers)	☐ Product Removal ☐ On-site device modifications/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ None ☐ Other:
5	Are there any future follow-up actions not mentioned in the Safety alert and can't be done in the meantime?	☐ No ☐ Yes, Details:
6	Specify the deadline date to complete all corrective actions	
7	Justification for the proposed deadline to complete all corrective actions	
8	Choose progress reports period (if completion deadline is longer than 3 months), a progress report includes: • *No. of notified customers with date and methods of communication* • *No. of customers responded* • *No. of corrected units per customer*	☐ Every Week ☐ Every 2 Weeks ☐ Every Month ☐ Every 2 Months ☐ Every 3 Months ☐ Other:
	The following documents should be provided when submitting this form.	
9	List of affected customers provided? (Facility name, City, No. of products per customer)	☐ Yes, Number of affected customers: ☐ No, Details:
10	Risk Assessment form provided?	☐ Yes ☐ No, Details:

I hereby confirm that I am the authorized person 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:	