FIELD SAFETY CORRECTIVE ACTION NOTIFICATION (FSCA) FORM

1. Before filling this form, the reporter collects and collates the prescribed information in the form.
2. This form will serve as the reporting tool in lieu with the Medical Devices Rules, 2017.
   Fourth Schedule
   [See rule 20(2), 21(2), 34(2), 63(1) and 64(1)] Part II (ii) (b) and Appendix II for intimating, notifying CDSCO for any Field Safety Corrective Action (FSCA) in relation to medical device product recall and other corrective action.
3. A scanned signed copy of PDF version of this form is to be sent to CDSCO via email to dci.nic.in
4. Additional information that may be pertinent for the completion of this form can be provided as an attachment.
5. All the field safety notices will be published on the CDSCO website and the reporter holds the full responsibility for the information contained in the Field Safety Notification and reporter must indemnify CDSCO for all losses, claims, demands, liabilities, causes of action, expenses of any kind arising from CDSCO's publication of the FSN.

Primary Information		
1.	**Type of Field Safety Corrective Action (FSCA)**	☐ Product Recall
		☐ Other Corrective actions
2.	**Type of Report**	☐ Notification
		☐ Preliminary Report
		☐ Final Report
3.	**Date of Report (dd/mm/yy)**	
4.	**Reference Number (auto generated by system)**	
Particulars of Reporters		
1.	**Contact Person Name**	
2.	**Job Title**	
3.	**Telephone Numbers**	
4.	**Email Address**	
5.	**Office Address**	
6.	**Local Contact Details (if reporter not based in India)**	

Device General Information		
1.	**Device Name**	
2.	**Accessories / Associated Devices Affected**	
3.	**Device Intended Use**	
Regulatory Details		
Other than India		
1.	**Device Regulatory Status**	Is the device registered globally ☐ Yes ☐ No
		Is the device marketed globally ☐ Yes ☐ No
		If yes provide details :
In India		
1.	**Device Regulatory Status**	Is the device registered in India ☐ Yes ☐ No
		Is the device marketed in India ☐ Yes ☐ No
		If yes provide details :
2.	**Manufacturer(s) and Contact Details**	
3.	**Product License Holder / Local Authorized Representative Name & Address**	
4.	**Importer(s) / Distributor(s) and Contact Details**	
Impacted Device Information		
1.	**Model Number**	
2.	**Catalogue Number**	
3.	**Serial Number**	
4.	**Affected Lot / Batch Number**	
5.	**UDI Number**	
6.	**Accessories / Associated Devices Affected**	

Device Related to FSCA Information		
1.	**Number of affected Unit**	**Manufactured in India**
		Period : (mm/yyy) to (mm/yyy)
		Imported into India
		Period : (mm/yyy) to (mm/yyy)
		Supplied in India
		Period : (mm/yyy) to (mm/yyy)
		Expected Shipment to India
		Expected Date of Arrival : (mm/yyy)
2.	**Number of affected units supplied to each consignee**	
3.	**FSCA Strategy**	
4.	**Did the FSCA arise due to an adverse event?**	☐ Yes ☐ No
5.	**If yes, what is the category of adverse event?**	☐ Serious Public Health Threat
		☐ Death
		☐ Serious Injury
		☐ Non-Serious Injury
6.	**Did this adverse event occur in India?**	☐ Yes ☐ No
		If Yes then adverse event Ref. No. & Summary :
7.	**Evaluation of risk associated with affected device (Health Hazard Evaluation Report)**	
8.	**Give reason & detail for FSCA (if other than the adverse event)**	

Affected Device Details (e.g. device identifiers, lot/batch No.) listed in the FSCA Communication		
For Other than India		
1.	**Has the FSCA communication been sent to all consignees?**	
2.	**Date of commencement of FSCA by product owner (dd/mm/yyy)**	
3.	**Date of commencement of FSCA (if applicable)**	
4.	**Countries to which FSCA has been reported (if any)**	
5.	**Proposed date of completion of FSCA (if applicable)**	
6.	**Summary of root cause analysis**	
7.	**Summary of Corrective and Preventive Action (CAPA)**	
For India		
1.	**Affected device details**	
2.	**Has the FSCA communication been sent to all consignees?**	☐ Yes, Date Sent : (dd/mm/yyy) ☐ No (dd/mm/yyy) Expected Date to be sent :
3.	**Date of commencement of FSCA by product owner (dd/mm/yyy)**	
4.	**Date of commencement of FSCA in India (if applicable)**	
5.	**Countries to which FSCA has been reported (if any)**	
6.	**Proposed date of completion of FSCA (if applicable)**	

7.	**Summary of root cause analysis**	
8.	**Summary of Corrective and Preventive Action (CAPA)**	
Change Notification (if applicable)		
1.	**Type of change (software change, design change, labelling)**	
2.	**For software change, have any feature not related to FSCA incorporates**	☐ Yes ☐ No If Yes then provide details :
Other Information		

I attested that the information submitted is true and accurate and that I am authorized to submit this form in behalf of company.

Signature : ……

Name of reporting person : ……

Date of Notification : ……