



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) | <input type="checkbox"/> Product Recall |
| | | <input type="checkbox"/> Other Corrective actions |
| 2. | Type of Report | <input type="checkbox"/> Notification |
| | | <input type="checkbox"/> Preliminary Report |
| | | <input type="checkbox"/> 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 <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | | Is the device marketed globally <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | | If yes provide details : |
| In India | | |
| 1. | Device Regulatory Status | Is the device registered in India <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | | Is the device marketed in India <input type="checkbox"/> Yes <input type="checkbox"/> 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/yyyy) to (mm/yyyy) |
| | | Imported into India |
| | | Period : (mm/yyyy) to (mm/yyyy) |
| | | Supplied in India |
| | | Period : (mm/yyyy) to (mm/yyyy) |
| | | Expected Shipment to India |
| | Expected Date of Arrival : (mm/yyyy) | |
| 2. | Number of affected units supplied to each consignee | |
| 3. | FSCA Strategy | |
| 4. | Did the FSCA arise due to an adverse event? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 5. | If yes, what is the category of adverse event? | <input type="checkbox"/> Serious Public Health Threat |
| | | <input type="checkbox"/> Death |
| | | <input type="checkbox"/> Serious Injury |
| | | <input type="checkbox"/> Non-Serious Injury |
| 6. | Did this adverse event occur in India? | <input type="checkbox"/> Yes <input type="checkbox"/> 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/yyyy) | |
| 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? | <input type="checkbox"/> Yes, Date Sent : (dd/mm/yyyy) <input type="checkbox"/> No (dd/mm/yyyy) Expected Date to be sent : |
| 3. | Date of commencement of FSCA by product owner (dd/mm/yyyy) | |
| 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 | <input type="checkbox"/> Yes <input type="checkbox"/> 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 :