# Field Safety Corrective Action (FSCA) For Medtech Companies:

A field safety corrective action is an action initiated by an organization to ensure that it eliminates the risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. Such actions, whether associated with direct or indirect harm, should be reported and should be notified via a field safety notice.

| Sl. No. | Criteria for Field Safety Corrective Action (FSCA) | We shall comply, a procedure exists | Currently we don't have a procedure to comply |
|---|---|---|---|
| I. | If the failure might lead to or might have led to death or serious deterioration in the state of health associated with the use of a medical device and has an impact on a product that has already been placed on the market, the manufacturer or organization must initiate a FSCA | COMMENTS | COMMENTS |
| II. | If associated with direct or indirect harm, shall be reported and will be notified via a field safety notice. | COMMENTS | COMMENTS |
| III. | A device modification, which may be permanent or temporary changes, to the labelling or instructions for use. | COMMENTS | COMMENTS |
| IV. | The organization shall inform users of an error on the labelling of their device which indicates a shelf life longer than the validated shelf life for the product. | COMMENTS | COMMENTS |
| V. | Software upgrades (if applicable) following the identification of a fault in the software version already in the field. | COMMENTS | COMMENTS |
| VI. | Advice given by the organization may include modification to the clinical management of patients/samples to address a risk of death or serious deterioration in state of health related specifically to the characteristics of the device | COMMENTS | COMMENTS |

| Sl. No. | Management of FSCA | We shall comply, a procedure exists | Currently we don't have a procedure to comply |
|---|---|---|---|
| I. | The FSCA may include:<br>the return of a medical device | COMMENTS | COMMENTS |
| II. | device modification | COMMENTS | COMMENTS |
| III. | device exchange | COMMENTS | COMMENTS |
| IV. | device destruction | COMMENTS | COMMENTS |
| V. | retrofit by purchaser of manufacturers modification or design change advice given by manufacturer regarding the use of the device and/or the follow up of patients, users or others (e.g. where the device is no longer on the market) | COMMENTS | COMMENTS |

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| Sl. No. | Analysis of serious incidents and FSCA: | We shall comply, a procedure exists | Currently we don't have a procedure to comply |
|---|---|---|---|
| I. | Upon reporting of a serious incident pursuant to Article 87(1), manufacturer shall, without delay, perform the necessary investigations in relation to the serious incident and the devices concerned. This shall include a risk assessment of the incident and field safety corrective action. | COMMENTS | COMMENTS |
| II. | Manufacturer shall co-operate with the competent authorities and notified body during the investigations and shall not perform any investigation which involves altering the device or a sample of the batch concerned in a way which may affect any subsequent evaluation of the causes of the incident, prior to informing the competent authorities of such action. | COMMENTS | COMMENTS |
| III. | Manufacturer shall provide a final report to the competent authority setting out its findings from the investigation by means of electronic system, whenever required. | COMMENTS | COMMENTS |
| IV. | Manufacturer shall ensure that information about the field safety corrective action taken is brought, without delay, to the attention of users of the device in question by means of a **field safety notice**.<br><br>***NOTE**: The field safety notice shall be edited in an official Union language or languages determined by the Member State in which the field safety corrective action is taken. Except in cases of urgency, the content of the draft field safety notice shall be submitted to the evaluating competent authority to allow it to make comments.* | COMMENTS | COMMENTS |
| V. | The field safety notice shall allow the correct identification of the device or devices involved, in particular by including<br><br>• the relevant UDIs<br><br>• the correct identification<br><br>• including the SRN, if already issued. | COMMENTS | COMMENTS |
| VI. | The field safety notice shall explain,<br><br>• in a clear manner, the reasons for the field safety corrective action with reference to the device malfunction and associated risks for patients, users or other persons, and<br><br>• shall clearly indicate all the actions to be taken by users. | COMMENTS | COMMENTS |
| VII. | Manufacturer shall enter the field safety notice in EUDAMED, whenever required, once such process is activated. | COMMENTS | COMMENTS |

NOTE: Adverse events and Field Safety Corrective Actions (FSCA) would be reported as per **Article 92 (5) & (7) of MDR 2017/745** to the respective National Competent Authority of EEA. Further, reports will be submitted to the competent authority using the electronic system whenever required.

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**Reference:**

1. Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.
2. MEDDEV 2.12-1 rev.8 Vigilance Jan 2013; Guidelines on a Medical Devices Vigilance System
3. ISO 13485:2016 (E) – Medical Devices – Quality Management systems – requirements for regulatory purposes; Clause 8.2.3 Reporting to regulatory authorities.

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