

10.5 ANNEX 5 - Template for a Field Safety Notice

Urgent Field Safety Notice

Commercial name of the affected product,

FSCA-identifier (e.g. date)

Type of action (e.g. chapter 4 definition of a FSCA).

Date:

Attention: ////////////////

Details on affected devices:

Specific details to enable the affected product to be easily identified e.g. type of device, model name and number, batch/ serial numbers of affected devices and part or order number. Insert or attach list of individual devices.

(Possible reference to a manufacturer web site.)

Description of the problem:

A factual statement explaining the reasons for the FSCA, including description of the device deficiency or malfunction, clarification of the potential hazard associated with the continued use of the device and the associated risk to the patient, user or other person.

Any possible risk to patients associated with previous use of affected devices.

Advise on action to be taken by the user:

Include, as appropriate:

- identifying and quarantining the device,*
- method of recovery, disposal or modification of device*
- recommended patient follow up, e.g implants, IVD*
- timelines.*
- Confirmation form to be sent back to the manufacturer if an action is required (e.g. return of products)*

Transmission of this Field Safety Notice: (if appropriate)

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (If appropriate)

Please transfer this notice to other organisations on which this action has an impact. (If appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (if appropriate)

Contact reference person:

Name / organisation, address, contact details. MEDDEV 2 12-1 rev. 8 Vigilance

The undersign confirms that this notice has been notified the appropriate Regulatory Agency
(Closing paragraph)
Signature