Questions and Answers to fill in the Field Safety Notice (FSN).

GENERAL QUESTIONS	
What was the scope of the FSN project?	Agree a common FSN form for communication of field safety corrective actions within EU. This common form applies only to FSNs targeted at Health Care Professionals
Should the manufacturer/authorized representative provide the same information in FSN as already provided in FSCARF (FSCA Report Form) to the CA?	No, FSN provides information to users. FSCA Report Form is the place for information needed only by NCAs. There will inevitably be some overlap of information across the two forms.
What level of detail is appropriate for inclusion in the FSN?	Include enough information to help/protect users, but not too much to confuse/dilute message
How should information be ordered within each section?	Present information in order of importance, or time sequence of measures to implement, if possible.
Do all fields have to be completed for every FSN?	No, only the fields indicated by * (in red) are considered essential for all FSNs and form the minimum expected content. The titles of different sections are indicated in red and should be maintained, because some of the items inside are considered essential. Where the manufacturer chooses not to include information suggested in the optional fields, these fields/rows should be deleted from the final FSN with sections renumbered or numbering deleted.
Should I complete l the form using free text?	

		Be aware that some of the sections contains scroll-down menus. They can be recognized by the field “choose an item”. Different options come up when clicking this field. You only have to select the most suitable in your case. Where formatted text is to be entered, it may be easier to prepare this separately and copy it, rather than enter directly into the template, as formatting may be lost. Copying with the template in “Developer, Design Mode” may also help retain formatting.
Once the FSN has been reviewed and approved by the coordinating Competent Authority (where the authorized representative or manufacturer is located), can any further changes be requested by NCAs?		Yes, NCAs still have the right to request changes to the draft FSN based upon issue specific or local needs, but this should be in exceptional circumstances and kept to a minimum.
Once the amended FSN form is available will it be mandatory?		No it cannot be mandatory as it is not defined within the Directives or new regulations. However, industry is strongly encouraged to use this form whenever possible in the interests of consistency to help the user. Each regional area of the manufacturer’s website (where relevant) where FSNs are posted should include the FSN in the format distributed in that territory. Where different formats have been used globally, alternative version may be posted alongside, if the manufacturer considers this necessary to illustrate they address the same action.
Cover Page		
For Attention of	Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.	The information should be sufficient to identify the recipient of this FSN. Usually, the FSN indicates only the role of the recipient. This should as a minimum identify the professional roles of individuals and names where this level of detail is known. If the intention is to identify recipients by name, the manufacturer should indicate this in the version provided to the competent authorities and add the name in the customised FSN for the specific customer.
1. Information on Affected Devices		
1.1 Device Type(s)	Brief description of the device(s). Consider including a	Which information should be addressed in this point? - All the necessary information so that the user could identify the affected devices, this includes the most important details that assure this identification: description of the

	photo where this would help with identification	device, including photos where possible. The aim is to facilitate users identify the device.
1.2 Commercial name(s)	Add as Appendix if necessary.	What is meant by commercial name? - The name given to the affected MEDICAL DEVICE in the labelling/IFU and/or CE certificate or Declaration of conformity. - If the MEDICAL DEVICE is known by other denomination in the professional practice it would be advisable to add it also (in brackets) What if several MEDICAL DEVICEs are involved? All of them have to be listed. If a large number of items need to be included, it may be advisable to provide them in an appendix
1.3 Unique Device Identifier (UDI)	Complete when this becomes available.	What is the meaning of UDI? - Unique Device Identifier (UDI-DI) The UDI-DI is a unique numeric or alphanumeric code specific to a model of medical device and that is also used as the "access key" to information stored in a UDID. Examples of the UDI-DI include GS1 GTIN (Global Trade Item Number), HIBC-LIC (Labeler Identification Code), ISBT 128-PPIC (Processor Product Identification Code). For more information, see the UDI Guidance Unique Device Identification (UDI) of Medical devices produced by the International Medical Device Regulators Forum (9 December 2013) How do you have to proceed if there are several devices involved? *The UDI can be provided as an appendix if necessary depending how many need to be listed.*
1.4 Primary clinical	How the device(s)	

purpose of device(s)	is/are used in the clinical setting/intended use.	What does “Primary clinical purpose of the device”’ means? - A brief explanation of the use given to the medical device or how it is used in the clinical practice should be addressed.
1.5 Device Model/Catalogue/part number(s)	Add as Appendix if necessary.	Provide all the necessary details to identify the affected Medical device. Example: - List of different sizes of dental screws. - List of different presentations containing different volumes of a reagent. What if several MEDICAL DEVICEs are involved? All of them have to be listed. If a large number of items need to be included, it may be advisable to provide them in an appendix
1.6 Software version	Only where relevant.	This section should only be complete if the MEDICAL DEVICE has a software component which is affected by the FSCA.
1.7 Affected serial or lot number range	Where relevant. Add as Appendix if necessary or provide web-link.	This section has to be completed only when the affected MEDICAL DEVICE are included in a specific range of lots or serial number. Example: - Serial number in a ventilator - Lot number in a reagent If it is a wide range or very detailed, provided in an attachment or a web-link if it is necessary. If lot or serial number information is not available, manufacturing, distribution, release or expiration dates for affected product should be specified.
1.8 Associated devices	Eg for IVD reagents and platforms.	What if the MEDICAL DEVICE is part of a system or it is used with other MEDICAL DEVICEs

		(accessories or not) that could be affected indirectly by the corrective action? - When the device(s) affected by the corrective action is related/ used with/ linked to other MEDICAL DEVICEs in the clinical practice, these associated MEDICAL DEVICEs should be listed in this section. Examples: ○ IVD. A reagent and the analyzer used with ○ The software of X-ray/RMN system, a glucometer, an analyzer, etc. ○ The administration sets and the infusion pump ○ Paddles and defibrillator ○ A part of a hip implant as the stem ○ A specific equipment used to implant a prosthesis
2. Reason for Field Safety Corrective Action (FSCA)		
2.1 Description of the product problem	Where there is one. Maybe "none" if eg Field Safety Notice (FSN) is to reinforce instructions for use.	
2.2 Hazard giving rise to the FSCA	Details of the greatest threat to the patient/end user as a consequence of not following the advice. Make clear whether risk is to user, patient or both. Should also try to indicate the residual risk of the FSN advice/action is taken.	Details should be provided for both direct and indirect harm. Example: "in vitro device" indirect risk for Public health (contagious illness). What would happen in case of not following the advice? Examples: - In vitro: if previous results are not reviewed, patients that are actually ill won´t be treated. - Implanted patients won´t be followed up and their illness could become worst. Is there any residual risk, in case the advice is followed? Provide details.

		Example: - Implanted patients. Yes. Device-related, complications may occur (possibly detected as a result of special patient follow-up) (metallosis, etc.) - Software upgrade. No, the problem is solved and is not going to happen again.
2.3 Probability of problem arising	Provide an indication (from incident data or prospective modelling) of the likelihood the problem will arise.	From the data the manufacturer has on number of incidents reported as a fraction of the number of devices distributed or implantable, it should be possible for estimates to be made on the likelihood of future incidents. Depending upon the nature of the issue and the statistical modelling possible, the manufacturer may choose to express the chance of an incident or of an injury in either a qualitative (ie low, medium, high) or quantitative way.
2.4 Predicted risk to patient/users	From risk assessment process indicate the expected likelihood/severity of patient/end user harm (direct or indirect).	This concept combines the severity of the hazard with the probability that it may arise, to give an overall patient risk. This conclusion will emanate from the manufacturer's risk assessment process . At most the HHE conclusion should be referenced here, but any greater level of detail is likely to be more inappropriate for inclusion within the FSCARF. Consideration should be given to prediction of the risk of a negative health outcome for different patient groups, compared with the whole population carrying this type of medical device, taking also into account the severity of the incident. As above, depending upon the nature of the issue and the statistical modelling possible, the manufacturer may choose to express the risk of an incident or of an injury to the patient or end user in either a qualitative (ie mild/moderate/severe) or quantitative way.
2.5 Further information to help characterize the problem	Include any further relevant information or	Same comment above

	statistics to help convey the seriousness of the issue.	
2.6 Background on Issue	Eg how the manufacturer became aware; brief details of relevant incidents; root cause if known; rationale for containment of problem to only affected devices; other risk mitigation or longer-term preventative action etc.	How the manufacturer became aware? Examples: - "X" incidents reported by users. - During technical inspection of the medical device , the failure was detected. Which is the root cause if known? Examples: - A software failure detected. - In vitro. Use of a reagent that increases the background signal (Example: Bovine Serum Albumin). Why this FSCA affect only to the listed set of products? Examples: - Only these products contain the "defective software mentioned above" - The defective reagent was used only with the listed range of lots. What other actions can the user take to prevent this from happening in future? Example: - Periodic technical inspections and implement updates to the software. Any other action to help the effectiveness of the FSCA? Example: - Inform the people responsible for the equipment/ In vitro analysis. - Keep the notice close to the working area, etc.
2.7 Other information relevant to FSCA	This field may only contain additional information that is deemed necessary by	Include in this section possible alternative devices/treatments suggested by the manufacturer.

	the manufacturer to supplement information relevant to the FSCA.	
3. Type of Action to mitigate the risk		
3.1 Action to be taken by the User		Select and retain all the actions from the options listed which are required to be performed by the user and delete all others from the final version of the FSN. In case of two or more selections, is the order important? - Only in those cases where a sequential order is relevant. Example: Identify devices Quarantine devices Return devices
	Provide further details on the action(s) identified.	It is important to provide full details and clarification of the action(s) selected. This is mandatory when "Other (ensure full details are provided)" is selected as a "User action required"
3.2 By when should the action be completed?	Specify where critical to patient/end user safety or state "not time critical"	By when should the action be completed? - In cases where the user needs to finish the action(s) within a certain timeframe, specify the date. - This timeframe should be determined case by case. If it is not possible to provide a specified deadline a wording like "immediately" or "…as soon as possible, but no later than…" could be used. - If you provide a date, use the following format: yyyy/mm/dd - It is important to distinguish between the expected action from the user (options included in the scroll down) and the user acknowledgement. This deadline refers to the user action.

3.3 Particular considerations for: Choose an item.	Is follow-up of patients or patient results recommended? Choose an item. Provide further details of patient follow-up if required.	Select *a kind of device* from the first **scroll down** of the item list and select *yes or no* from the second **scroll down** of the item list. In affirmative case, answer the question "If yes, is follow-up of patients required?", and explain the details of this follow-up procedure in the field "Provide further details of patient follow-up required"
3.4 Is customer Reply Required? (If yes, form to be attached)	Choose an item.	Definition: Document used by the manufacturer to obtain positive confirmation that the user is aware of information and action detailed in Field Safety Notice, ie to monitor reconciliation of document receipt and action taken by the customer. Select "Yes" or "No" from the scroll down. This will not be required in all cases. The manufacturer should decide whether to use this depending on the type of medical device and the corrective action, on a case by case basis, Examples where this document would be advisable: -Withdrawal of the medical device. -Additional information on IFUs. -Situations where patients are involved such us: additional information should be provided to them or an additional clinical follow up is needed. -IVDs: shortness of expiry date, previous lab results should be revised or samples should be reprocessed.
3.5 Action Being taken by the Manufacturer		Select and retain all the actions from the options listed which are required to be performed by the manufacturer and delete all others from the final version of the FSN. In case of two or more items, is the order important? - Only in those cases where a sequential order is relevant, Example: On-site device modification/inspection/re-work Software upgrade

	Provide further details on the action(s) identified.	It is important to provide full details and clarification of the action(s) selected. This is mandatory when "Other (ensure full details are provided)" is selected as a "User action required"
3.6 By when should the action be completed?	Specify where critical to patient/end user safety or state "not time critical"	By when should the action be completed? - In cases where the manufacturer has a deadline to finish the action(s), specify the date, either a worldwide completion date or a local date. - In cases where the manufacturer cannot yet provide a deadline to finish the action(s) (eg software upgrade still under development), "unknown at present" should be specified
3.7 Is the FSN required to be communicated to the patient /lay user?	Choose an item.	One option, "Yes" or "No" need to be selected from the scroll down. The decision on the need for this further level of communication should be taken by the manufacturer as part of their risk assessment and mitigation strategy.
3.8 If yes, has manufacturer provide information suitable for the patient /lay user?	Attach patient/end user information letter/sheet if available.	If "Yes" is selected in the previous question (3.7), the manufacturer should confirm whether further information directed to the patient/end user has been prepared and included as an attachment to the FSN. The format of the patient/lay user communication should be determined by the manufacturer on a case-by-case basis.

4. General Information

4.1 FSN Type(s)	Choose an item (scroll)	Select "new" or "update".
4.2 For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant	This section only has to be completed if this is an update of a previous FSN. It is important to provide the reference number of the manufacturer and the date.

4.3 For Updated FSN, key new information as follows	Summarise any key difference in devices affected and/or action to be taken.	This section only has to be completed with the new issues about the device affected and/or the action to be taken.
4.4 Further advice or information already expected in follow-up FSN?	Choose an item	Select “yes”, “no” or “not yet know” from the scroll of the item list.
If Yes:		
4.5 If follow-up FSN expected, what is the further advice expected to relate to:	Example: Patient management, device modifications…	
4.6 Anticipate timescale for follow-up FSN	For provision of updated advice	
4.7 Manufacturer information	a. Company name	Only necessary if not evident on letter
	b. Address	Only necessary if not evident on letter
	c. Website address	Only necessary if not evident on letter
4.8 The Competent (Regulatory) Authority of your country has been informed about this communication to customers.		It is important that the FSN states that the NCA within whose jurisdiction the FSN is being distributed has been informed about the corrective action. This is not just the coordinating NCA, but each affected NCA, in compliance with directive 98/79/EC of the European parliament and of the council of 27 October 1998 on *in vitro* diagnostic medical devices This could be achieved via the generic statement in the template, or could be adapted for each country to identify the relevant NCA by name.

4.9 List of attachments/appendices:	If extensive consider providing web-link instead.	Example: Technical Service Bulletin, Addendum IFU, Update Surgical Technical.
4.10 Name/Signature	Insert Name and Title here and signature below	
Transmission of this Field Safety Notice		
This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organizations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative as this provides important feedback		Other organisations which may be impacted by the action may include those to which test results from the use of device have been sent, or where patients have been transferred for ongoing follow-up activities.