Rev 1: September 2018

FSN Ref: Manufacturer's ref number FSCA Ref: Manufacturer's ref number

Date: DD:MMM:YYYY.

# Urgent Field Safety Notice
# Device Commercial Name

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.

| Contact details of local representative (name, e-mail, telephone, address etc.)* |
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| This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages |

Company Name/Logo

Rev 1: September 2018

FSN Ref: Manufacturer's ref number FSCA Ref: Manufacturer's ref number

# Urgent Field Safety Notice (FSN)
# Device Commercial Name
# Risk addressed by FSN

| 1. Information on Affected Devices* | |
|---|---|
| 1. | 1. Device Type(s)* |
| | Brief description of the device(s) in plain language, including whether supplied sterile. Consider including a photo (here or in an Annex) where this would help with identification |
| 1. | 2. Commercial name(s) |
| | Add as Appendix if necessary. |
| 1. | 3. Unique Device Identifier(s) (UDI-DI) |
| | Complete when this becomes available. |
| 1. | 4. Primary clinical purpose of device(s)* |
| | How the device(s) is/are used in the clinical setting/intended use. |
| 1. | 5. Device Model/Catalogue/part number(s)* |
| | Add as Appendix if necessary. |
| 1. | 6. Software version |
| | Only where relevant. |
| 1. | 7. Affected serial or lot number range |
| | Where relevant. If not known, use manufacturing/distribution/expiration date as appropriate. Add as Appendix if necessary or provide web-based look-up tool. |
| 1. | 8. Associated devices |
| | Within context of the FSCA eg for IVD reagents and platforms. |

| 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 hazard to the patient/end user that the advice/action is intended to mitigate. Make clear whether risk is to user, patient or both. Should also try to indicate the residual risk if the FSN advice/action is taken. |
| 2. | 3. Probability of problem arising |
| | Provide an indication (from incident data or prospective modelling) of the likelihood the problem will arise. |
| 2. | 4. Predicted risk to patient/users |
| | From the output of the Health Hazard Evaluation indicate the anticipated risk (product of severity x probability) of patient/end user harm (direct or indirect). |
| 2. | 5. Further information to help characterise the problem |
| | Include any further relevant 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. |
| 2. | 7. Other information relevant to FSCA |
| | This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA. |

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| | **3. Type of Action to mitigate the risk*** |
| 3. | **1. Action To Be Taken by the User*** <br> ☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device <br> ☐ On-site device modification/inspection <br> ☐ Follow patient management recommendations <br> ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) <br> ☐ Other ☐ None <br> Provide further details of the action(s) identified. |
| 3. | 2. By when should the action be completed? — Specify where critical to patient/end user safety |
| 3. | 3. Particular considerations for: Choose an item. <br> Is follow-up of patients or review of patients' previous results recommended? Choose an item. <br> Provide further details of patient-level follow-up if required or a justification why none is required |
| 3. | 4. Is customer Reply Required? * (If yes, form attached specifying deadline for return) — Choose an item. |
| 3. | **5. Action Being Taken by the Manufacturer** <br> ☐ Product Removal ☐ On-site device modification/inspection <br> ☐ Software upgrade ☐ IFU or labelling change <br> ☐ Other ☐ None <br> Provide further details of the action(s) identified. |
| 3 | 6. By when should the action be completed? — Specify where critical to patient/end user safety |
| 3. | 7. Is the FSN required to be communicated to the patient /lay user? — Choose an item. |
| 3 | 8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? <br> Choose an item. Choose an item. |

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| | **4. General Information*** | |
| 4. | 1. FSN Type* | Choose an item. |
| 4. | 2. For updated FSN, reference number and date of previous FSN | Provide reference and date of previous FSN if relevant |
| 4. | **3.** For Updated FSN, key new information as follows: | |
| | Summarise any key difference in devices affected and/or action to be taken. | |
| 4. | 4. Further advice or information already expected in follow-up FSN? * | Choose an item. |
| 4 | 5. If follow-up FSN expected, what is the further advice expected to relate to: | |
| | Eg patient management, device modifications etc | |
| 4 | 6. Anticipated timescale for follow-up FSN | For provision of updated advice. |
| 4. | 7. Manufacturer information<br>(For contact details of local representative refer to page 1 of this FSN) | |
| | a. Company Name | Only necessary if not evident on letter-head. |
| | b. Address | Only necessary if not evident on letter-head. |
| | c. Website address | Only necessary if not evident on letter-head. |
| 4. | 8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * | |
| 4. | 9. List of attachments/appendices: | If extensive consider providing web-link instead. |
| 4. | 10. Name/Signature | Insert Name and Title here and signature below |

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| | **Transmission of this Field Safety Notice** |
| | 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. (As appropriate)<br><br>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)<br><br>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.<br><br>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..* |

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.