Date: 08/10/2021
From: [redacted]/MHRA

To [redacted]
cc [redacted]
bcc

Subject [redacted]

MHRA ref: [redacted] quote this in any reply

Your ref: [redacted]

Thank you for your report.

If this is not your final report, we expect your next report by the date you stated in your report. We will check if you have sent it to us.

If you don,t have all the information immediately available, you can send us a follow-up report but tell us when you expect to send us the final report.

Follow up or Final reports should be sent in the same way that you originally reported. If you submitted your report on MORE, edit the submission and re-submit on MORE. If you submitted a MIR form by email or XM information and re-submit ensuring you include the MHRA ref [redacted] in this exact format, in field 1.1c 'Reference number assigned by NCA for this incident' on the MIR form to ensure the correct file is updated and to prevent duplication. Any related MHRA User Report reference number should only be added in 'Healthcare facility report number' Field 3.4c on the MIR form.

Following receipt of a final report, we will not +close, a record nor provide a +closure, confirmation as we continually monitor reports through signal detection. We will contact you if we require more information.

If this incident leads to a field safety corrective action (FSCA), your FSCA report with FSN form must be sent separately to the final report. Submit as a new report via MORE and provide the extra information, as detailed in the annex below, in the Description of the FSCA tab on MORE or fill in this form (Field Safety Corrective Action, Medical Devices Vigilance System, MEDDEV 2.12/1 rev 7) and provide extra information in box 7 of the form. We will log your FSCA on our database and send you a new reference number.

If this report relates to an serious adverse event (SAE) resulting from a clinical investigation, please continue to report in line with the requirements set out in the MHRA,s letter of no objection.

Yours sincerely
Adverse Incidents & Communications Team
MHRA, Devices

Note: From 1st August 2021 we will not log any new vigilance reports that are not submitted via our Manufacturer,s On-line Reporting Environment (MORE) or by sending an XML output of the Manufacturer Incident Report (MIR) form to aicxml@mhra.gov.uk. An email will be sent informing you that your report has not been logged and will contain guidance on how to correctly log your vigilance report. Please be aware that until your report is correctly logged you will not have met the legal obligations under vigilance.

Use this email address aic@mhra.gov.uk to contact us. We check it regularly.

You can access the Medical Device Safety Officer (MDSO) contact list via MORE in order to copy them in on communications regarding Field Safety Notices (FSNs). This can help you ensure appropriate targeting and prompt action of the FSN within the MDSO,s organisation.

Annex: Extra information we need in section 7 of your FSCA report

1. Risk assessment for the FSCA including:
1.1. How many incidents have you received related to this FSCA?
1.2. What is the hazard presented by using the device with this issue? Send us a copy of the Health Hazard Evaluation (HHE) or Clinical risk assessment report.
1.3. If this is a batch issue, why it is restricted to these batches only?
1.4. Do you know if this issue affects other CE-marked devices? (eg own-brand labelled products).
1.5. Provide update on root cause investigation / conclusions of tests and other investigations on suspect or other samples.
1.6. Provide details of long-term corrective actions.

2. Where the FSCA applies to the UK:
2.1. What is the FSN distribution list (named contacts and locations)? Include any additional people who will be sent the letter (chief executives, Medical Device Safety Officers (MDSOs), medical directors, community pharmacists etc). You can send us this as a separate document.
2.2. How will you contact the end user if affected customers include distributors? Send us a copy of the list of distributors. Confirm who will be managing the FSCA and compiling reconciliation data for these end users.
2.3. How many sites are affected in the UK? How many devices/tests did each site receive?
You can send us this as a separate document.
2.4. When was the affected product distributed/installed?
2.5. How will you monitor the extent to which the FSN message has been received? (eg fax-back form / telephone follow-up). What are your key dates for actions?
2.6. How many UK sites have confirmed receipt of your FSN?
2.7. How many UK sites have confirmed that they have successfully undertaken the action(s) specified in your FSN?
2.8. What is the expected date of completion of the field safety corrective action?

3. Provide regular updates on points 2.6 and 2.7