Liyana

From: Zaidi <zaidi.jantan@diagnosticare.com.my>
Sent: Tuesday, 12 November, 2024 4:16 PM
To: siti.noorliyana@diagnosticare.com.my; noa@diagnosticare.com.my
Subject: FW: Field Safety Corrective Action-LIAISON QSET Device Plus (319060)
Attachments: Distributor Importer Reply Form.docx

From: Mehta, Nivya <nivya.mehta@diasorin.com>
Sent: Tuesday, 12 November, 2024 4:08 PM
To: Zaidi <zaidi.jantan@diagnosticare.com.my>; jiafei.wong@diagnosticare.com.my; norasyikin@diagnosticare.com.my; siti.sarah@diagnosticare.com.my; akmal@diagnosticare.com.my
Cc: Lim Kevin <kevin.lim@diasorin.com>; Buczenski Yannick <yannick.buczenski@diasorin.com>; Goh Andrea <andrea.goh@diasorin.com>
Subject: Field Safety Corrective Action-LIAISON QSET Device Plus (319060)

Hi DCARE team

FIELD SAFETY CORRECTIVE ACTION

Product: LIAISON® Q.S.E.T. Device Plus

Part No: 319060

Batch/ No:

225084	233154	223244
230094	259144	224244
219104	228174	251234
232094	236174	252244
224124	210204	223274
217134	221214	221294
234114	228224	232294
205144	229224	222314

Action: "In Field Safety Corrective Action (FSCA)"

Notification to Competent Authority: Is required because this action is being taken to reduce a risk to health.

Attachments: Field Safety Notice in English

Dear all,
This In Field Safety Corrective Action has been initiated because 0.14% of the tubes in the affected kit lots of LIAISON® Q.S.E.T. Device Plus have loose clear caps. The loose clear caps may allow leakage of the buffer from the tube.

The root cause of the problem is under investigation.

A stool sample prepared with less than the correct amount of buffer may cause a false high Calprotectin or Elastase patient result. The tests provide information on the clinical suspicion of exocrine pancreatic insufficiency and/or the delineation of inflammatory bowel disease versus irritable bowel syndrome. In both conditions, the test result is information but is not confirmatory. The holistic review of all other diagnostic and therapeutic information is used to inform the clinician of the definitive diagnosis. The retrospective review of the test results will bear no impact on the ability to refine treatment decisions in the majority of cases, and it is anticipated that the patients potentially impacted by exposure to the nonconforming test result will receive a definitive treatment plan. Therefore, review of past patients results is not deemed necessary.

Actions to be taken by the user:

- Devices should be inspected for loose clear caps prior to use. The user should confirm that the clear cap is tight by grasping the cap and twisting. If the cap is loose, the device should be discarded. Do not attempt to use the device as the loose clear cap may have allowed the buffer to leak and the buffer volume may be insufficient.

In addition, if you have distributed this product, you must identify all customers that have received the affected product and notify them within two days through the Urgent Field Safety Notice translated in your local language (English is provided as attachments of this e-mail).

Dear Diasorin Distributors:

Please be so kind as to provide us with the Distributor/Importer Reply Form (herewith attached) within one month.

- As far as Credit Note requests, you need to send the Distributor/Importer Reply Form to: **nivya.mehta@diasorin.com**

Nivya Mehta

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