
From:
Sent: Tuesday, April 16, 2019 3:38 PM
To:
Cc:
Subject: Linkage Biosciences, Inc. - Initial FSCA Report (Mfr Ref: MW 19-001)
Attachments: MW 19-001 SureTyper v6.0.0 Rev01.pdf; MW 19-001 HHE signed final.pdf; LBI MW 19-001 FSCA final.pdf; LBI MW 19-001 FSCA final_data.xml

Categories: CRM
LinkPointReference: <referencePacket id="ff6c389a-af22-44a8-b0b9-6b08c2a1adf9"> <referenceItem tableName="Contact" key="003400001Tr8BA" doNotSync="0" tableCaption="Contact" description=">

MHRA Devices
151 Buckingham Palace Road- London SW1W 9SZ

Dear Sir / Madam,

Emergo Europe, as the Authorized Representative, is writing to provide you with the Initial FSCA Report for our client Linkage Biosciences, Inc. (South San Francisco, CA, USA).

Type of report: Initial FSCA Report

Type of risk/Background Information: When a session is opened in SureTyper v 6.0.0 for the first time, the software is not detecting the instrument that the raw data is generated on and the instrument specific parameters are not being loaded resulting in default parameters being used and loaded. This may cause incorrect test results as the Tm window and peak ratio may not be correct. No injuries have been reported to date.

Corrective Actions: A field safety notice (FSN MW 19-001) is to be sent to end users. The software in question has been removed from distribution and a new version with bug fixed shall be released shortly. This field action is sufficient as there is no risk of death or serious harm to the patient as a result because transplant decisions are made based on multiple factors and all homozygous results must be confirmed. In addition, the Instruction for Use state that the device should not be used as the sole basis for making a clinical decision. Please reference Health Hazard Evaluation for MW 19- 001.

If you would like to discuss this matter further, or require any additional documentation, please do not hesitate to contact Emergo Europe at EmergoVigilance@ul.com.

Yours sincerely,

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