



**medical
systems**

To
IGZ
Dutch Healthcare Inspectorate
P.O. Box 2680, NL- 3500 BS Utrecht
Email: meldpunt@igz.nl

Reference: Field Safety Corrective Action FSCA_2021001

Dear Ladies and Gentlemen,

By this letter, I wish to inform you of the closure of a field safety corrective action concerning Premium Line devices manufactured by B Medical Systems S.à r.l. in Luxembourg.

On 12 July 2021, a customer complaint was received from the *Établissement Français du Sang Occitanie*, Montpellier, France, regarding a B401 blood bank refrigerator, serial number 9352208, manufactured by B Medical Systems S.à r.l. in 2019. The customer reported that the temperature displayed by the unit was 3.9°C, while the actual air temperature inside the unit, measured by an independent thermometer, was above 20°C. After an internal investigation, we found that the problem was related to a software error in the installed firmware version 5.8.

An FSCA report according to MEDDEV 2.12/1 rev. 8 and a Field Safety Notice (FSN) detailing the problem and the planned field actions were submitted directly to the French authority ANSM. The corrective measures were also implemented in all European countries, including Finland.

Due to the lack of implementation of the EUDAMED vigilance module, it was decided at that time to communicate the FSN and the FSCA only to ANSM in France.

You will find the final report of the FSCA attached for your information.

If you have any questions or wish to obtain any further documents, please do not hesitate to contact me.

With my best regards,

xxx

Stamp and signature of approval holder

06.12.2021

Date