

## **Voluntary optimization of some drainage set LiquoGuard® 7**

Fulda, 27.03.2023: MÖLLER Medical GmbH has detected leakage of the Drainage Set LiquoGuard® 7 in the course of use in isolated cases as part of its ongoing quality and market monitoring processes.

The company reports that the use of the Drainage Set LiquoGuard® 7 may result in isolated cases of CSF leakage, limited to a few batches. This may not be immediately recognizable.

Patient well-being and user safety are of utmost importance to MÖLLER. The company takes isolated leaks with the theoretical risk of unnoticed overdrainage seriously. Therefore, the Fulda-based medical device manufacturer acts proactively and initiates an immediate voluntary recall.

Affected is the Drainage Set LiquoGuard® 7 (REF. No. 000035011411) of the following lot numbers (LOT):

AUE115, AXC843, AXY401, AYJ829, AYJ849, AZB143, AZB144, AZD848, AZF324, AZQ420, AZQ421, AZR977, AZX892, AZX893, AZX897.

All other products or batches are not affected.

Affected customers will be informed separately by MÖLLER.

The company has thoroughly investigated the individual cases. In the course of giving the highest priority to patient safety, MÖLLER has decided to technically optimize the Drainage Sets, although they meet the specifications.

All LiquoGuard® 7 tube sets will be technically improved at the tube connection points to increase their stability.

In order to make the voluntary recall as smooth as possible for its customers, MÖLLER is offering free collection of the affected products. Alternatively, customers can return the products directly to MÖLLER for safe disposal. Replacement deliveries of the optimized tube sets will be made automatically from the end of May 2023, without any further action required on the side of the customer. Until then, customers are requested to use alternative treatment methods.

MÖLLER would like to thank its customers for their quick assistance and for the active exchange with users, which makes the continuous product improvements possible in the first place. In addition, the company apologizes to the affected customers for the inconvenience caused.