

2021-02-03

URGENT - FIELD SAFETY NOTICE

Subject: FSCA-2021-01-29 Return of HLS samples from Market

Affected Product:

REF	Product Description	Article No.
BE-HLS 7050	HLS Set Advanced 7.0	70106.9073

Affected Lot No.: 70144667

Dear valued customer,

The HLS Set Advanced is intended for use in an extracorporeal circulation for cardiac support and/or pulmonary support.

Maquet Cardiopulmonary GmbH has become aware that one lot of HLS Set being defined as test sample for Product Performance Qualification (PPQ) has been released to the market. The products of this affected lot were manufactured according to current technical documentation except attaching additional warning labels. Further, the products were labelled with a yellow label written "Sample" and a label written "Not for clinical use" on all packaging levels, as indicated in the picture below



Taking into consideration that

- a healthcare practitioner will visually inspect each product before use and not use any product that is labeled as "Sample" and "Not for clinical use", and
- the product is sterile and meets all functional requirements

no adverse effects would occur to patient or user.

Please do not use the affected products listed above and return them to your local Getinge representative to get replacement.

Maquet Cardiopulmonary GmbH has not received any reports of serious injuries or death due to release of PPQ samples to customers.

Corrective Action:

- Please return immediately all affected products in your stock to your local Getinge Representative for replacement.

Advice on action to be taken by the User

- According to our surveillance documentation, your current stock may include products affected by this action.
- Please complete and sign the attached Letter of Acknowledgement for the customer and send it back to your local Getinge representative.

Referenced documents/ attachments:

- Letter of Acknowledgement Customer

Transmission of the Field Safety Notice:

- This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
- Please transfer this notice to other organizations on which the action has an impact.
- Please maintain awareness of the notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.

We apologize for any inconvenience this may cause you and we will do our utmost to carry through this action as swiftly as possible.

As required, we will provide this notification to the necessary Regulatory Agencies.

Should you have questions or require additional information, please contact your local Getinge representative, or send an e-mail to FSCA.cp@getinge.com.

Sincerely,

Managing Director

Safety Officer

Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY