URGENT FIELD SAFETY NOTICE

Subject: 745922 - HLS & PLS Set - potentially compromised sterile barrier

Affected Product:

REF no.	Article no.	Product description
BE-PLS 2050	701068386	SPLS Set
BE-PLS 2051	701068389	SPLS Set Plus
BO-PLS 2051	701068390	S/ HIT Set PLS Plus
BE-PLS 2050	701076706	PLS China
BE-HLS 7050	701069073	SHLS Set Advanced 7.0
BE-HLS 5050	701069076	SHLS Set Advanced 5.0
BO-HLS 7050	701069083	S/HIT Set Advanced 7.0
BEQ-HLS 7050-CA	701069065	SHLS Set Advanced 7.0
BEQ-HLS 5050-CA	701069068	SHLS Set Advanced 5.0
BEQ-HLS 7050 USA	701069078	SHLS Set Advanced 7.0
BEQ-HLS 5050 USA	701069077	SHLS Set Advanced 5.0

Affected Batch No.: See Annex I List of affected batches included below

Unique Device Identifier:

REF no.	Article no.	UDI
BE-PLS 2050	701068386	04058863006635
BE-PLS 2051	701068389	04058863006666
BO-PLS 2051	701068390	04058863006673
BE-PLS 2050	701076706	04058863304533
BE-HLS 7050	701069073	04058863005744
BE-HLS 5050	701069076	04058863078298
BO-HLS 7050	701069083	04058863020082
BEQ-HLS 7050-CA	701069065	04058863300238
BEQ-HLS 5050-CA	701069068	04058863304625
BEQ-HLS 7050 USA	701069078	04058863080383
BEQ-HLS 5050 USA	701069077	04058863076355

Dear valued customer,

The HLS Set Advanced and the PLS Set are intended for use in an extracorporeal circulation for pulmonary and/ or cardio-circulatory support.

Maquet Cardiopulmonary GmbH (MCP) has received a communication from a regulatory body in which the conformity of the products mentioned above was discussed due to not adequately performed packaging tests. Although no customers' complaints were received due to this potential non-conformity, Maquet Cardiopulmonary GmbH (MCP) voluntarily decided to establish a quality shipping-hold of the aforementioned products on December 8th, 2022.

Parallel to that, the respective tests were repeated with samples under market conditions. The samples are conditioned as described in the current market specification; single sterilized and transport conditioned according to ASTM D4169-22. However, the test samples were not double sterilized to cover an assumed worst condition of sterilization impact.

Health-Hazard-Evaluations (HHEs) were performed to assess the risk of the potential non-conformities, including the results of the newly performed tests, resulting in a justifiable risk according to the current product Risk Management Plan. The HHEs documented as possible risks:

Exposure to a non-sterile or potentially non-sterile medical device, or a delay in the procedure, may result in following immediate and/ or long-range health consequences:

- *Inflammation, Infection, Sepsis,*
- *Ischemia*
- *User Inconvenience*

Maquet Cardiopulmonary GmbH is working with all possible urgency on the finalization of the required tests also in the case of double sterilization to cover the worst condition of sterilization impact. However, these test results will be available earliest in April 2023. Thereafter, we will reassess whether further measures need to be taken to ensure patient safety.

Therefore, at this time we can only provide you with devices with the potential non conformity described above.

Action to be taken: **Due to a potential delay of replacement products:**

<u>Option 1</u>

- Return all affected products in your stock to your local Getinge representative.
- In case of return of the affected products, please contact your local Getinge representative for credit.
- If a product is already in use, it should remain in use.

<u>Option 2:</u>

- If the products are urgently necessary based on expert clinical judgement, you can use the devices by following the Instruction for use.
- Regardless of the decision you make, please complete and sign the attached customer response form and send it back to your local Getinge representative.
- Please report any adverse events, e.g. infections potentially related to the affected products to your Getinge Representative.

Regardless of the decision you make (option 1 or 2), please complete and sign the attached customer response form and send it back to your local Getinge representative.

Enclosed documents:

- customer response form
- Annex I List of affected batches

Transmission of the Field Safety Notice:

- This notice needs to be forwarded to all those who need to be aware within your organization or to any organization where the potentially affected devices may have been further distributed.
- 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 caused and assure you that we are working on a solution with highest priority. 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.

Sincerely,

Managing Director

Signature: Dieter Engel *Electronically signed by: Dieter Engel Reason: I approve this document. Date: Dec 30, 2022 21:00 GMT+1*

Email: dieter.engel@getinge.com

Person Responsible for Regulatory Compliance (PRRC)

Signature: Timur Güvercinci *Electronically signed by: Timur Güvercinci Reason: I approve this document. Date: Dec 30. 2022 21:14 GMT+1*

Email: timur.guevercinci@getinge.com

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CUSTOMER RESPONSE FORM

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Affected Batch No.: See Annex I List of affected batches included below

☐ I have read and understand this Field Safety Notice for above mentioned affected products.

☐ I confirm that I have distributed this Field Safety Notice to the affected personal.

☐ All affected products have been consumed.

☐ Following affected products will be returned to you for credit.

REF	Article Number	Description	Batch Number	Quantity

Your Comments:

Country	Hospital / Clinic (full address)
Date	Name (Function)
	Signature

Please return the completed form to your local Getinge representative by email enter local Getinge mail address or via post enter local Getinge address or FAX>:

Annex I List of affected batches

This Annex I List of affected batches is considered as a supplementary attachment to the 745922 Field Safety Notice.

Below are listed all batches of products which are affected and have been distributed.

Table 1 general overview

REF	Article	Batch range
BE-PLS 2050	701068386	All batches affected
BE-PLS 2051	701068389	All batches affected
BO-PLS 2051	701068390	All batches affected
BE-PLS 2050	701076706	All batches affected
BE-HLS 7050	701069073	All batches affected
BE-HLS 5050	701069076	All batches affected
BO-HLS 7050	701069083	All batches affected
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