2024-08-08

URGENT FIELD SAFETY NOTICE

Manufacturer SRN:	DE-MF-000020091
FSCA Reference:	1064512 – CTP – Potentially missing component
FSN Type:	New
Affected Product:	BO-HQV 15907#Neonate Pack van 0.9-1.5 lt (Article no. 701067041) BO-HQV 140901#Ossigenatore neonatale (Article no. 701076520) HQV 140701#Pack Standard VKMO 11000 (Article no. 701076522)
Unique Device Identifier(s) (UDI-DI):	04037691959757 (Article no. 701067041) 04058863302928 (Article no. 701076520) 04058863302942 (Article no. 701076522)
Affected Batch No.:	3000383804 (Article no. 701067041) 3000383802 (Article no. 701076520) 3000383798 (Article no. 701076522)
For Attention of:	Users of the medical device listed above

Dear valued customer,

Maquet Cardiopulmonary GmbH (MCP) would like to inform you with this letter about a recall for three batches of Custom Tubing Packs (CTP).

The HLM tubing set is intended for use in extracorporeal circulation during cardiopulmonary bypass procedures.

Problem description

Maquet Cardiopulmonary GmbH became aware of this issue through a stock discrepancy of 18 units of a component. Consequently, components are potentially missing from 18 CTPs. The component in question is a sterile bag containing tight caps for the reservoir. These tight caps are required for vacuum-assisted venous drainage (VAVD).

Therefore, the scope of this field action was narrowed down to these 18 units.

Hazardous situation

Maquet Cardiopulmonary GmbH determined the following potential hazardous situations:

- Patient is exposed to inappropriately low blood flow

Potential harm

The following possible immediate and/or long-range health consequences were be determined (for further information please refer to Annex I):

- Ischemia (low risk)

Maquet Cardiopulmonary GmbH has identified no relevant customer complaints for the affected material.

Corrective Action:

- Return of affected devices

Action to be taken by the user:

☒ Identify Device
☒ Quarantine Device
☒ Return Device
☐ Destroy Device

Details of the further action(s):

- According to our post-market surveillance documentation, you may have products affected by this action. Please examine your inventory immediately to determine, if you have any affected product in your inventory.
- Please quarantine and return immediately all affected products in your stock to your local Getinge representative.
- Upon return of the affected products, please contact your local Getinge representative for credit or replacement.
- Please **always** report any adverse events, e.g., infections potentially related to the affected products, to your Getinge representative.
- Duly fill out the enclosed Letter of Acknowledgement and return it to your local Getinge representative by **August 30, 2024,** the latest. Please give **FSCA-1064512** as reference in the subject line of your email.

Action to be taken by the manufacturer:

☒ Product Removal
☐ On-site device modification/ inspection
☐ Software upgrade
☐ IFU or labelling change
☒ Other
☐ None

- Inform all customers possessing the affected products **promptly** about this Field Action by sending the Field Safety Notice for Customers.

Enclosed documents:

- Customer response form
- Annex I Further information regarding Hazardous situation, Harms and Risk Levels

Transmission of the Field Safety Notice

- Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are made aware of this Urgent Field Safety Notice.
- Please transfer this notice to other organizations on which the action has an impact.
- If you have given the products to third parties, please forward a copy of this information or inform the contact person indicated below.
- Please maintain awareness on the notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.

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

As required, we have provided 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 (on behalf of the)

Signature: *Electronically signed by: Johannes Schlenker Reason: I approve this document. Date: Aug 8, 2024 13:05 GMT+2*

Email: johannes.schlenker@getinge.com

Person Responsible for Regulatory Compliance (PRRC)

Signature: *Electronically signed by: Alexander Bernhardt Reason: I approve this document. Date: Aug 8, 2024 12:57 GMT+2*

Email: alexander.bernhardt@getinge.com

Contact details of manufacturer

Alexander Bernhardt
Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY
Phone: +49 7222 932 - 0
Email: FSCA.cp@getinge.com

CUSTOMER RESPONSE FORM

FSCA Reference:	1064512 – CTP – Potentially missing component
Affected Product:	BO-HQV 15907#Neonate Pack van 0.9-1.5 lt (Article no. 701067041) BO-HQV 140901#Ossigenatore neonatale (Article no. 701076520) HQV 140701#Pack Standard VKMO 11000 (Article no. 701076522)
Affected Batch No.:	3000383804 (Article no. 701067041) 3000383802 (Article no. 701076520) 3000383798 (Article no. 701076522)

Please send this form at the latest by **August 30, 2024,** to your local Getinge representative.

By completing this document and signing it, I acknowledge that I have read and understand the following associated points:

- I have read and understand this Field Safety Notice for all products with VHK 71000 reservoir. We will take action as soon as possible according to given instructions.
- I confirm that I have distributed this Field Safety Notice to the affected personal.

☐ I do not have any affected products in my inventory.
☐ I have following affected products in my inventory:

Article No.	Description	Batch No.	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 Further information regarding Hazardous situation, Harms and Risk Levels

This Annex I Further information regarding Hazardous situation, Harms and Risk Levels is considered a supplementary attachment to the 1064512 Field Safety Notice.

Hazardous situation	Harm	S	P	Risk		
				Low	Med	High
Patient is exposed to inappropriately low blood flow	Ischemia	4	2	☒	☐	☐

Severity Definitions:
Negligible (1) Inconvenience or temporary discomfort of patient, user or third party. No medical intervention or follow-up treatment is required
Low (2) Temporary injury or disability of patients, users or third parties. No medical intervention or follow up treatment is required.
Critical (3) Temporary injury or disability of patients, users or third parties. Medical intervention or follow-up treatment is required.
Catastrophic (4) Permanent injury or disability (e.g., loss of a body part), a life-threatening situation or death of patients, users or third parties

Probability Definitions:
Improbable (1) Harm is not likely
Remote (2) Harm occurs infrequently
Occasional (3) Harm may occur occasionally / intermittently
Probable (4) Harm may occur often
Frequent (5) Harm will occur repeatedly