

2023-09-28

**URGENT FIELD SAFETY NOTICE****Manufacturer SRN:** DE-MF-000020091**FSCA Reference:** 874275 – Custom Tubing Pack – Gas filter used in fluid lines**FSCA Type:** New**Affected Product:**

REF no.	Article no.	Product description
<b>HQV 3300</b>	701004874	Quadrox Complete Pack with HMO
<b>S 1150</b>	701019904	Kondenzwasser-Falle
<b>BO-HQV 51601</b>	701041635	Adult Pack OPEN
<b>BO-HQV 27903</b>	701053602	Adult Pack
<b>HQV 94500</b>	701072923	Cabaret de pompe Chicoutimi
<b>BO-H 141906</b>	701076649	Rotaflow supply set Suction

**Affected Batch No.:** See attached Annex I List of affected lots**Unique Device Identifier:**

REF no.	Article no.	UDI
<b>HQV 3300</b>	701004874	04037691005003
<b>S 1150</b>	701019904	04037691270234
<b>BO-HQV 51601</b>	701041635	04037691380216
<b>BO-HQV 27903</b>	701053602	04037691718156
<b>HQV 94500</b>	701072923	04058863080284
<b>BO-H 141906</b>	701076649	04058863303765

**For Attention of:** Users of the medical devices listed above

Dear valued customer,

Maquet Cardiopulmonary GmbH (MCP) would like to inform you with this letter about a recall for the above-mentioned Custom Tubing Packs (CTP) due to inappropriately deployed gas filters in fluid-bearing lines of the product.

The Heart-Lung-Machine (HLM) CTP is a component of an extracorporeal system and may only be used in combination with other components (e.g., blood pumps, oxygenators, hemoconcentrators, heat exchangers). It is used to transport blood and other fluids between the patient and the extracorporeal system. The HLM CTP is intended for use in extracorporeal circulation during cardiopulmonary bypass procedures.

### Problem description

Maquet Cardiopulmonary GmbH became aware of the issue in course of a customer complaint. It was reported that there was gas leaking from the cardioplegia line. The customer did not replace the product during treatment. No harm to any person has been reported. Upon investigation of the complaint, it was noted that the gas filter of the HLM CTP was not deployed as specified by the manufacturer (i.e., in gas-bearing line/tube).

### Hazardous situations

In course of a Health Hazard Evaluation (HHE), MCP determined the following hazardous situations for the inappropriate deployment of the gas filters:

- Patient, user or other persons are exposed to pathogenic agents.
- The patient is exposed to inappropriate low blood flow.
- Patient is exposed to inappropriately high pressure.
- Product exchange/replacement.

### Potential harms

The possible immediate and/or long range health consequences of the nonconformance include the following:

- Inflammation
- Infection
- Sepsis
- Ischemia
- Hypertension
- User inconvenience

Maquet Cardiopulmonary GmbH has not identified any complaints of patient harm, serious injuries, or deaths due to failure mode described above.

**Corrective Actions**

- Recall of all affected products

**Action to be taken by the customer:**

- |   |   |
|---|---|
| <input checked="" type="checkbox"/> Identify Device | <input checked="" type="checkbox"/> Quarantine Device |
| <input checked="" type="checkbox"/> Return Device   | <input type="checkbox"/> Destroy Device               |

- 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 Custom Tubing Sets in your inventory.
- Please return immediately all affected products in your stock to your local Getinge representative.
- Alternative products are available. Upon return, Getinge will provide you with Credit Note. Replacements can be ordered as usual.
- If a product is already in use, it should remain in use.
- 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 **October 31, 2023, the latest**. Please give **FSCA-874275** as reference in the subject line of your email.

**Action to be taken by the manufacturer**

- |   |  |
|---|--|
| <input checked="" type="checkbox"/> Product Removal | <input type="checkbox"/> On-site device modification/ inspection |
| <input type="checkbox"/> Software upgrade           | <input type="checkbox"/> IFU or labelling change                 |
| <input type="checkbox"/> Other                      | <input type="checkbox"/> None                                    |

- Inform all customers possessing the affected products **promptly** about this Field Action by sending the Field Safety Notice for Customers.
- Upon return of affected products, provide customer with credit note.

**Enclosed documents**

- Customer response form
- Annex I List of affected lots

**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 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 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](mailto:FSCA.cp@getinge.com).

Sincerely,

**Managing Director**

**Signature:** *Dieter Engel*

Electronically signed by: Dieter Engel  
Reason: I approve this document.  
Date: Sep 28, 2023 14:57 GMT+2

**Email:** dieter.engel@getinge.com

**Person Responsible for Regulatory  
Compliance (PRRC)**

**Signature:** *Tom Peters*

Electronically signed by: Tom Peters  
Reason: I approve this document.  
Date: Sep 28, 2023 15:40 GMT+2

**Email:** tom.peters@getinge.com

Maquet Cardiopulmonary GmbH  
Kehler Str. 31  
76437 Rastatt  
GERMANY  
Phone: +49 7222 932 - 0  
Email: [FSCA.cp@getinge.com](mailto:FSCA.cp@getinge.com)

## CUSTOMER RESPONSE FORM

**FSCA Reference:** 874275 – Custom Tubing Pack – Gas filter used in fluid lines**Affected Product:**

REF no.	Article no.	Product description
<b>HQV 3300</b>	701004874	Quadrox Complete Pack with HMO
<b>S 1150</b>	701019904	Kondenzwasser-Falle
<b>BO-HQV 51601</b>	701041635	Adult Pack OPEN
<b>BO-HQV 27903</b>	701053602	Adult Pack
<b>HQV 94500</b>	701072923	Cabaret de pompe Chicoutimi
<b>BO-H 141906</b>	701076649	Rotaflow supply set Suction

**Affected Batch No.:** See attached Annex I List of affected batchesPlease send this form to your local Getinge representative at the latest by **October 31, 2023**.

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 CTP products. 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 CTP in my inventory.☐ I have following affected CTP in my inventory and will send them back for credit:

Product Name	Article Number	Batch Number	Quantity

Your Comments:

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Country

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Hospital / Clinic (full address)

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**FIELD SAFETY NOTICE**



**DMS No.:** 3269030 V 02

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\_\_\_\_\_  
Date

\_\_\_\_\_  
Name (Function)

\_\_\_\_\_  
Signature

Please return the completed form to your local Getinge representative by email, via post or FAX.

**Annex I List of affected lots**

This Annex I List of affected lots is considered as a supplementary attachment to the 874275 Field Safety Notice.

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

Material Number	Material Description	Lot Number	Country
701072923	HQV 94500#Cabaret de pompe Chicoutimi	3000147946	Canada
701072923	HQV 94500#Cabaret de pompe Chicoutimi	3000148855	Canada
701072923	HQV 94500#Cabaret de pompe Chicoutimi	3000172880	Canada
701072923	HQV 94500#Cabaret de pompe Chicoutimi	3000199082	Canada
701072923	HQV 94500#Cabaret de pompe Chicoutimi	3000221116	Canada
701072923	HQV 94500#Cabaret de pompe Chicoutimi	3000162713	Canada
701072923	HQV 94500#Cabaret de pompe Chicoutimi	3000192526	Canada
701072923	HQV 94500#Cabaret de pompe Chicoutimi	3000206013	Canada
701072923	HQV 94500#Cabaret de pompe Chicoutimi	3000209354	Canada
701072923	HQV 94500#Cabaret de pompe Chicoutimi	3000252905	Canada
701072923	HQV 94500#Cabaret de pompe Chicoutimi	3000141558	Canada
701072923	HQV 94500#Cabaret de pompe Chicoutimi	3000159328	Canada
701072923	HQV 94500#Cabaret de pompe Chicoutimi	3000171796	Canada
701072923	HQV 94500#Cabaret de pompe Chicoutimi	3000194211	Canada
701019904	S 1150#Kondenzwasser-Falle	92302793	Germany
701019904	S 1150#Kondenzwasser-Falle	3000162011	Germany
701019904	S 1150#Kondenzwasser-Falle	3000156733	Germany
701019904	S 1150#Kondenzwasser-Falle	92312197	Germany
701019904	S 1150#Kondenzwasser-Falle	3000144901	Germany
701004874	HQV 3300#Quadrox Complete Pack with HMO	92311752	Ireland
701004874	HQV 3300#Quadrox Complete Pack with HMO	92311966	Ireland
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000196717	Ireland
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000196719	Ireland
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000214150	Ireland
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000219309	Ireland
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000210366	Ireland
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000231129	Ireland
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000233559	Ireland
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000236120	Ireland
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000239972	Ireland
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000196716	Ireland
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000202555	Ireland

701004874	HQV 3300#Quadrox Complete Pack with HMO	3000213283	Ireland
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000215267	Ireland
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000239973	Ireland
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000239974	Ireland
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000266352	Ireland
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000141837	Ireland
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000143122	Ireland
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000143297	Ireland
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000144304	Ireland
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000270194	Ireland
701041635	BO-HQV 51601#Adult Pack OPEN	3000177705	Netherlands
701041635	BO-HQV 51601#Adult Pack OPEN	3000178795	Netherlands
701041635	BO-HQV 51601#Adult Pack OPEN	3000188694	Netherlands
701041635	BO-HQV 51601#Adult Pack OPEN	3000190250	Netherlands
701041635	BO-HQV 51601#Adult Pack OPEN	3000214157	Netherlands
701041635	BO-HQV 51601#Adult Pack OPEN	92302824	Netherlands
701041635	BO-HQV 51601#Adult Pack OPEN	3000141561	Netherlands
701041635	BO-HQV 51601#Adult Pack OPEN	3000183012	Netherlands
701041635	BO-HQV 51601#Adult Pack OPEN	3000185421	Netherlands
701041635	BO-HQV 51601#Adult Pack OPEN	3000196030	Netherlands
701041635	BO-HQV 51601#Adult Pack OPEN	3000209132	Netherlands
701041635	BO-HQV 51601#Adult Pack OPEN	3000212338	Netherlands
701076649	BO-H 141906#Rotaflow supply set Suction	3000215247	Netherlands
701041635	BO-HQV 51601#Adult Pack OPEN	3000144965	Netherlands
701041635	BO-HQV 51601#Adult Pack OPEN	3000164620	Netherlands
701041635	BO-HQV 51601#Adult Pack OPEN	3000251718	Netherlands
701041635	BO-HQV 51601#Adult Pack OPEN	3000251719	Netherlands
701041635	BO-HQV 51601#Adult Pack OPEN	92305551	Netherlands
701041635	BO-HQV 51601#Adult Pack OPEN	92307328	Netherlands
701041635	BO-HQV 51601#Adult Pack OPEN	3000144964	Netherlands
701053602	BO-HQV 27903#Adult Pack	3000160122	Norway
701053602	BO-HQV 27903#Adult Pack	92304922	Norway
701053602	BO-HQV 27903#Adult Pack	92311980	Norway