

2023-08-21

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
HQV 3300	701004874	Quadrox Complete Pack with HMO
S 1150	701019904	Kondenzwasser-Falle
BO-HQV 51601	701041635	Adult Pack OPEN
BO-HQV 27903	701053602	Adult Pack
HQV 3003	701070115	Pre-Connected Circuit
HQV 94500	701072923	Cabaret de pompe Chicoutimi
BO-H 141906	701076649	Rotaflo supply set Suction

Affected Batch No.: See attached Annex I List of affected lots

Unique Device Identifier:

REF no.	Article no.	UDI
HQV 3300	701004874	04037691005003
S 1150	701019904	04037691270234
BO-HQV 51601	701041635	04037691380216
BO-HQV 27903	701053602	04037691718156
HQV 3003	701070115	04037691996325
HQV 94500	701072923	04058863080284
BO-H 141906	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:

- Identify Device
- Return Device
- Quarantine Device
- 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

- Product Removal
- Software upgrade
- Other
- On-site device modification/ inspection
- IFU or labelling change
- 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.

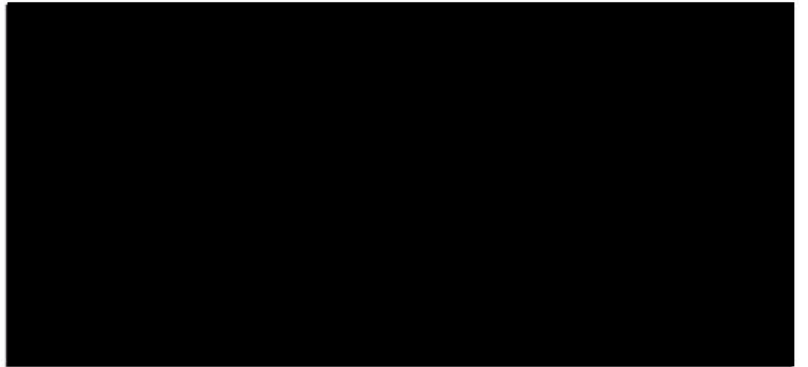
As required, we have provided this notification to the necessary Regulatory Agencies.

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

Sincerely,

Managing Director
(on behalf of the Managing Director)

**Person Responsible for Regulatory
Compliance (PRRC)**
(on behalf of the PRRC)



Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY
Phone: +49 7222 932 - 0
Email: 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
HQV 3300	701004874	Quadrox Complete Pack with HMO
S 1150	701019904	Kondenzwasser-Falle
BO-HQV 51601	701041635	Adult Pack OPEN
BO-HQV 27903	701053602	Adult Pack
HQV 3003	701070115	Pre-Connected Circuit
HQV 94500	701072923	Cabaret de pompe Chicoutimi
BO-H 141906	701076649	Rotaflo supply set Suction

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

Please 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:

Country

Hospital / Clinic (full address)

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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](#)>:

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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
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000147946	Canada
701004874	HQV 3300#Quadrox Complete Pack	3000148855	Canada
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000172880	Canada
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000199082	Canada
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000221116	Canada
701041635	BO-HQV 51601#Adult Pack OPEN	3000162713	Canada
701041635	BO-HQV 51601#Adult Pack OPEN	3000192526	Canada
701041635	BO-HQV 51601#Adult Pack OPEN	3000206013	Canada
701041635	BO-HQV 51601#Adult Pack OPEN	3000209354	Canada
701070115	HQV 3003#Pre-Connected Circuit	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
701004874	HQV 3300#Quadrox Complete Pack with HMO	92302793	Germany
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000162011	Germany
701053602	BO-HQV 27903#Adult Pack	3000156733	Germany
701072923	HQV 94500#Cabaret de pompe Chicoutimi	92312197	Germany
701072923	HQV 94500#Cabaret de pompe Chicoutimi	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	3000214150	Ireland
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000219309	Ireland
701019904	S 1150#Kondenzwasser-Falle	3000210366	Ireland
701019904	S 1150#Kondenzwasser-Falle	3000231129	Ireland
701019904	S 1150#Kondenzwasser-Falle	3000233559	Ireland
701019904	S 1150#Kondenzwasser-Falle	3000236120	Ireland
701019904	S 1150#Kondenzwasser-Falle	3000239972	Ireland
701041635	BO-HQV 51601#Adult Pack OPEN	3000196716	Ireland
701041635	BO-HQV 51601#Adult Pack OPEN	3000202555	Ireland

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701041635	BO-HQV 51601#Adult Pack OPEN	3000213283	Ireland
701041635	BO-HQV 51601#Adult Pack OPEN	3000215267	Ireland
701053602	BO-HQV 27903#Adult Pack	3000239973	Ireland
701053602	BO-HQV 27903#Adult Pack	3000239974	Ireland
701053602	BO-HQV 27903#Adult Pack	3000266352	Ireland
701072923	HQV 94500#Cabaret de pompe Chicoutimi	3000141837	Ireland
701072923	HQV 94500#Cabaret de pompe Chicoutimi	3000143122	Ireland
701072923	HQV 94500#Cabaret de pompe Chicoutimi	3000143297	Ireland
701072923	HQV 94500#Cabaret de pompe Chicoutimi	3000144304	Ireland
701076649	BO-H 141906#Rotaflow supply set Suction	3000270194	Ireland
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000177705	Netherlands
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000178795	Netherlands
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000188694	Netherlands
701004874	HQV 3300#Quadrox Complete Pack with HMO	3000190250	Netherlands
701004874	HQV 3300#Quadrox Complete Pack with HMO	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
701041635	BO-HQV 51601#Adult Pack OPEN	3000215247	Netherlands
701053602	BO-HQV 27903#Adult Pack	3000144965	Netherlands
701053602	BO-HQV 27903#Adult Pack	3000164620	Netherlands
701053602	BO-HQV 27903#Adult Pack	3000251718	Netherlands
701053602	BO-HQV 27903#Adult Pack	3000251719	Netherlands
701072923	HQV 94500#Cabaret de pompe Chicoutimi	92305551	Netherlands
701072923	HQV 94500#Cabaret de pompe Chicoutimi	92307328	Netherlands
701072923	HQV 94500#Cabaret de pompe Chicoutimi	3000144964	Netherlands
701041635	BO-HQV 51601#Adult Pack OPEN	3000160122	Norway
701070115	HQV 3003#Pre-Connected Circuit	92304922	Norway
701072923	HQV 94500#Cabaret de pompe Chicoutimi	92311980	Norway

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