2021-07-23

URGENT - FIELD SAFETY NOTICE

Subject: FSCA-2021-07-19 Tubing sets – incomplete system verification of sets with integrated 3rd party arterial filters

Affected Product: Tubing sets

REF	Product Description	Article number
BE-H 30803	Filtro Arterial Neonatos	701018952
BE-HQV 34708-1	Adult Closed System with	701064517
BE-HQV 34708-2	Adult Closed System with	701069147
BE-HQV 51608	Adult Perfusion Set	701073988
BE-HQV 64704	MECC system	701074327
BE-HQV 89202	XVIVO Disposable Lung Circu	701069387
BE-MECC 101403	MECC system w/o Reservoir	701075208
BE-MECC 50310	National UK NRP Pack	701071853
BE-MECC 50310u	National UK NRP Pack	701075048
BEQ-HQV 89203	XVIVO Disposable Lung Cir	701071592
BO-H 81202	Neonate Perfusion Pack	701050629
BO-H 81203	Pediatric Perfusion Pack	701051078
BO-H 81204	Infant Perfusion Pack	701051079
BO-HQV 104100	EVLP Circuit	701066978
H 109401	Pediatric Tubing Pack	701070305
H 109402	Infant Pack	701070307
H 12217	Standard Pediatric Set w. Filter	701063544
H 32605	Set Pequeno	701066054
H 32606	Ped./Mediano Pack	701066055
H 37803	Clydebank Perfusion Pack	701045747
H 61900	Lineas 1/4x1/4	701043741
H 61902	Lineas 1/4x3/8	701056918
H 99100	Tubing Set for HMO 30000	701063568
HQV 89200	XVIVO Disposable Lung Circuit	701052184

Affected Batch No.: See Annex I List of affected products

Dear valued customer,

The tubing sets are designed for extracorporeal support in surgical interventions involving a cardiopulmonary bypass or other extracorporeal circulation.

The tubing sets are designed and created according to the specifications and requirements of individual customers. Each tubing set varies by tubing sizes and lengths, as well as by included components (e.g. oxygenator, arterial filter, hemoconcentrator etc.).

The above mentioned tubing sets have a third party arterial filter as a component. During a review of the technical documentation of all tubing sets, the Notified Body of Maquet Cardiopulmonary GmbH has identified the lack in the system testing of the tubing sets with an integrated third party arterial filter. It is not ensured that performance of all required parameters (flow rate, pressure and temperature) within tubing sets are given.

Taking into consideration that the third party arterial filters were not tested as a system, Maquet Cardiopulmonary GmbH is unable to confirm that the filter will always function as intended. An arterial filter that does not function as intended may lead to the following immediate and/or long-range health consequences (harms):

- Ischemia due to a reduction in flow through an arterial filter
- Ischemia due to inefficient reduction of gaseous and/or particulate microemboli by an arterial filter
- Hemolysis due to an increase in shear stress associated with increased pressure through an arterial filter

Maquet Cardiopulmonary GmbH has not received any reports of serious injuries or death due to the issue, described above.

Corrective Action:

- According to our surveillance documentation, your current stock may include products affected by this action.
- Please do not use the affected products listed above.
- Please segregate and return immediately all affected products in your stock to your local Getinge Representative for credit notes.

Advice on action to be taken by the User:

- Please complete and sign the attached Letter of Acknowledgement for the customer and send it back to your local Getinge representative.
- If all affected products already used: Please still sign the 'Letter of Acknowledgement Customer'.
- Please report any adverse events in regards to the affected products to your Getinge Representative.

Referenced documents/ attachments:

- Letter of Acknowledgement Customer
- Annex I List of affected products

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

GETINGE
Markus Medart, 2021-07-23 09:01:49+0200
Approved: u2895387, Managing Director

Safety Officer

GETINGE
Marc Zimmermann, 2021-07-23 10:26:07+0200
Approved: u2381503, Senior Manager Quality Engineering Product Development

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