

2021-10-28

**URGENT - FIELD SAFETY NOTICE**

**Subject:** FSCA-2021-10-15 Customized tubing sets – incorrect shelf life of integrated 3<sup>rd</sup> party components

**Affected Product:** Customized tubing sets

REF	Product Description	Article number
H 13171	Pediatric Hemoconcentrator Set	701003799
H 21900	Transplant Circu. Assist. Set	701004042
H 3000	Adult Complete Pack	701012218
BE-HQV 32400	HL - Pack	701018261
BE-HQV 25900	Complete Pack, closed	701018472
HQV 11505	Quadrox Komplett Set vorkonn.	701022687
H 45902	Custom Pack, Adult	701024959
HQV 35604	Pack Complet Adulte	701026741
H 51860	Cardioplegia Pack	701027379
BO-HQV 15902	Adult Pack	701035634
S 1883	Filterset	701040988
BO-S 1899	HLM Pack	701041555
HQV 11507	Quadrox Komplett Set mit Pumpe	701045607
BO-HQV 37201	Small Adult C.E.C 3/8	701046576
BO-HQV 63003	MINISET KYS PLUS Softline	701047490
BE-HQV 21607	Pack Circulatory Circuit	701048185
BE-HQV 35402	Volwassen gesloten systeem	701048452
BO-HQV 7600	Quadrox-i Complete	701050391
BO-HQV 59203	Cabaret 0 - 8 kg	701052098
BO-HQV 84800	Tubing Pack	701052210
HQV 85500	Complete Neonatal Pack with HM	701052272
HQV 85501	Complete Paediatric Pack with	701052273
HQV 85502	Complete Small Adult Pack with	701052274
BO-HQV 19701	HL Pack	701054255
BO-HQV 59206	Cabaret 25 kg	701054493
BO-HQV 59205	Cabaret 12 - 24 kg	701054497
HQV 41408	KAVD Set	701054587
BEQ-HQV 48707	Perfusion Tubing Pack with	701062275
HQV 97900	Adult Pack with Oxy w/o Plegio	701063206
HQV 98701	Pediatric Set	701063467
BE-HQV 34708-1	Adult Closed System with	701064517
BEQ-H 84702	3/8" Circulatory Pack	701065229
BEQ-H 48715	3/8 ART - 3/8 VEN STERILE PA	701065246
BEQ-H 48730	Perfusion Tubing Pack with	701066180
HQV 103800	Quadrox-Set, Erwachsene	701066470
BO-HQV 34513	Pack Pediatrique complet	701066742
HQV 85503	Miniaturised Neonatal Pack w/o	701067343
HQV 98201	Membrane Perfusion Pack	701068444
BO-H 92101	Circuito CEC	701068671
BE-H 85001	Closed Pediatric System	701068810
BE-HQV 34708-2	Adult Closed System with	701069147
H 32160	Cardioplegia del nido 1:4	701069385

BO-HQV 41412	HL Pack Closed	701069472
BO-HQV 5807	Membran Set	701070022
BO-HQV 81604	Adult Pack	701070040
HQV 3003	Pre-Connected Circuit	701070115
BO-H 55815	Heart Lung Pack w. Rotaflow	701070954
BO-H 55816	Small Adult 3/8-3/8 HeartLung	701070955
BO-H 52103	Circuito Adulto	701071916
BE-H 29702	Custom Pack Adult	701072098
BO-H 7904	Circuito Adulto	701072491
HQV 4510	HL - Set	701072545
BE-HQV 92101	Circuito CEC	701072948
BE-HQV 52604	HLM Pack	701074425

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

Dear valued customer,

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

Such 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, filter, hemoconcentrator etc.). The tubing sets in general are designed for 2 years shelf-life, from the manufacturing date.

However, during a review of the technical documentation of tubing sets, it was found out that there is not sufficient evidence to demonstrate the 2 year shelf life of the following 3<sup>rd</sup> party components integrated into the above mentioned tubing sets:

*Table 1 intended function, material information and shelf life of affected components*

Article Number	Description	Intended Function	Shelf Life
70000.0245	00245#1/4"(x1/8") Needle	Administering or withdrawing of fluid or gas	1 year
70103.1935	Centrifugal Blood Pump	Pumping of liquids during extracorporeal circulation	1 year
70000.0172	00172#Bakterien/Druckfilter	Channeling of fluids in extracorporeal circuits	1 year

Usage of these 3<sup>rd</sup> party components after their shelf life of 1 year may lead to the following immediate and/or long-range health consequences (i.e. injuries, illnesses, and/or harms) for patients:

- Air and/or particle embolism
- Ischemia
- Blood loss
- Hemodynamic instability
- User inconvenience

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

**Corrective Action:**

- Please segregate and return the affected products in your stock to your local Getinge Representative for credit notes.

**Advice on action to be taken by the User:**

- According to our surveillance documentation, your current stock may include products affected by this action.
- 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.
- For queries about replacement or alternative products please contact your local 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](mailto:FSCA.cp@getinge.com).**

Sincerely,

**Managing Director**

**Safety Officer**

Maquet Cardiopulmonary GmbH  
Kehler Str. 31  
76437 Rastatt  
GERMANY

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