2019-09-12

FSCA Number: FSCA-2019-09-11

FSCA Title: VHK and VKMO Adult / Small Adult – Sterile Barrier Integrity

Affected Product:

- 701063877 - VKMO 71000 #QUADROX-i HMO 71000+VHK71000
- 701064518 - VKMO 50000 #QUADROX-i HMO 50000+VHK71000
- 701064523 - VKMO 70000 #QUADROX-i HMO 70000+VHK71000
- 701064525 - VKMO 78000 #QUADROX-i HMO 70000+VHK70000
- 701064526 - VKMO 51000 #QUADROX-i HMO 51000+VHK71000
- 701064567 - BE-VKMO 71000 #QUADR-i HMO71000+VHK71000
- 701067941 - VKMO 78000 #SQUADROX-i HMO 70000+VHK7000
- 701067942- VKMO 70000 #SQUADROX-i HMO 70000+VHK7100
- 701067948 - BO-VKMO 70000 #SQUADR-i HMO70000+VHK7100
- 701067949 - VKMO 71000 #SQUADROX-i HMO 71000+VHK7100
- 701067951 - BO-VKMO 71000 #SQUADR-i HMO71000+VHK7100
- 701067956 - BE-VKMO 70000 #SQUADR-i HMO70000+VHK7100
- 701067957 - BE-VKMO 71000 #SQUADR-i HMO71000+VHK7100
- 701067962 - BO-VKMOD 71000 #SQUADROX-iD 71000+VHK7100
- 701067966 - VKMO 50000 #SQUADROX-i HMO 50000+VHK7100
- 701067968 - BO-VKMO 50000 #SQUADR-i HMO50000+VHK7100
- 701067969 - VKMO 51000 #SQUADROX-i HMO 51000+VHK7100
- 701067972 - BE-VKMO 51000 #SQUADR-i HMO51000+VHK7100
- 701068197 - BO-VKMO 51000 #SQUADR-i HMO51000+VHK7100
- 701062605 - VHK 71000#Venöses Reservoir VHK 71000
- 701063859 - BE-VHK 71000#Venöses Reservoir VHK 71000
- 701066420 - BO-VHK 71000-J#Venöses Reservoir VHK 710

Affected product details: For specific material numbers and Lots please refer to the attached Annex I: List of affected products

Description of the problem:

Dear valued customers,
cc to the Chairman Medical Board and relevant Head-of-Department

During verification testing of Adult/Small Adult VKMOs and VHK a potential impairment of the sterile packaging barrier was detected. Under unfavorable transport conditions, excessive movement of the device and

its accessories in the carton can lead to stress points that could compromise the sterile barrier of the packaging pouches.

Exposure to a non-sterile or potentially non-sterile medical device may result in infection-causing inflammatory like syndromes thereby deteriorating the clinical state of the patient. Additionally, infection may occur if the device is connected to the central circulatory system.

Individuals undergoing extracorporeal circulation usually develop inflammatory response due to the fact that human blood cells are exposed to foreign surface with a release of inflammatory mediators as the consequence. The most severe form is called systemic inflammatory response Syndrome (SIRS).

Maquet Cardiopulmonary has not received any complaints associated to serious injuries or death due to damage to the sterile barrier system of the VKMO or VHK.

Due to the potential impairment of the sterile packaging pouch, **do not use the VKMO Adult/Small Adult or VHK** of the affected lot numbers in Annex I.

We apologize for any inconvenience caused and assure you that we are working with highest priority on a solution.

Corrective Action:

- Please return immediately all affected products in your stock to your local Getinge representative.

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.
- Return immediately the affected products to your local Getinge representative for credit.

Referenced documents/ attachments:

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

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 Maquet representative.

Sincerely,

Managing Director [redacted]

Safety Officer [redacted]

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