2019-10-28

FSCA Number: FSCA-2019-10-17

FSCA Title: Yellow/Blue Bin packaging –Sterile Barrier Integrity

Affected Product:

Yellow Bin

701035710	BO-HQV 62900#Adult Set with Quadrox
701045404	HQV 7404#Quadrox "I" Pack
701047490	BO-HQV 63003#MINISET KYS PLUS Softline
701052876	HQV 84002#Infant pack with integrated HM
701054573	HQV 84003#Paediatric Pack with HMO 31000
701054988	BE-HQV 63005#MINISET KYS (MECC - Set)
701063206	HQV 97900#Adult Pack with Oxygenator w/o Plegiox
701068444	HQV 98201#Membrane Perfusion Pack
701070151	HQV 44202#Adult Pack with Oxygenator
701071787	HQV 86306#Infant 1/4x3/8 Set
701072966	BO-HQV 62903#Adult Set with Soft Bag

Blue Bin

701071848	BE-MECC 119200#Adult Pack
701071853	BE-MECC 50310#National UK NRP Pack
701072827	HQV 101702#Adult Tubing Pack
701073246	BO-HQV 15914#HLM Small Adult 51000

Affected product details: See attached Annex I

Description of the problem:

Dear valued customers,

During verification testing of the Yellow Bin packaging, a potential breach of the sterile packaging pouches of the accessories was detected.

The sterile bag of the accessories is packaged in a main sterile bag with the other products and the main sterile bag is placed in the Yellow or Blue Bin. The main sterile bag remained intact in all cases during its packaging test. In case of immediate use of the accessory, which are packaged in the primary bag, the sterility is guaranteed and the accessories are safe to use.

Corrective Action:

Do not store any accessories in the Yellow or Blue Bin for later use.

Advice on action to be taken by the user:

- The scope of this FSN encompasses all products packaged in the Yellow and Blue Bin, the batch numbers are listed in this document.
- According to our surveillance documentation, your current stock may include products affected by this action.
- Please fill and sign the attached Letter of Acknowledgement for customer and send it back to your local Getinge representative.

Referenced documents/ attachments:

- Annex I: List of affected products
- Letter of Acknowledgment 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 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 Maquet representative

Managing Director **Safety Officer**

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Maquet Cardiopulmonary GmbH

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GERMANY