2019-10-29

FSCA Number: FSCA-2019-10-10

FSCA Title: QUADROX-iD Pediatric – Sterile Barrier Integrity

Affected Product:

- 70104.7041 BE-HMOD 30000 QUADROX-iD Pediatric with BIOLINE Coating
- 70105.0330 BEQ-HMOD 30000-USA QUADROX-iD Pediatric with BIOLINE Coating

Affected product details: See attached Annex I.

Description of the problem:

Dear valued customers,

cc to the Chairman Medical Board and relevant Head-of-Department

During design verification tests Maquet Cardiopulmonary has determined that the sterile barrier system of the QUADROX-iD Pediatric oxygenator may be compromised during transportation. 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.

Additional tests on products returned from Getinge's Sales and Service Units revealed that the primary packaging of the QUADROX-iD Pediatric might be breached. The size of the breach is small, which may be difficult for the user to detect.

Exposure to a 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 with damage to the sterile barrier system or to serious injuries or death due to damage to the sterile barrier system of the QUADROX-iD Pediatric oxygenator.

Due to the potential impairment of the sterile packaging pouch, **do not use the QUADROX-iD Pediatric** of the affected lot numbers in Annex I.

We apologize for any inconvenience caused.

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 Getinge representative.

Sincerely,

Managing Director	Approved / Geprüft i.A. UTC 2019-10-29, 12:29:05	Signatory: Timothy Talcott (Sr. Dir. Quality Impr. Prog.)	[redacted]
Safety Officer	UTC 2019-10-29, 11:57:58	Signatory: Nursel Boelens (Director of Regulatory Affairs)	[redacted]

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