March 20, 2024

URGENT MEDICAL DEVICE – Removal
FSCA 8010762-01/08/2024-001-R
ROTAFLOW Centrifugal Pumps (RF-32 Pumps)

Product Description	Product Code / Part Number	UDI Device Identifier (DI)	Distributed Affected Lot Numbers:
BEQ-RF-32-USA RotaFlow Centrifugal Pump with BIOLINE Coating	701047554	**04037691530864**	3000286570; 3000325568; **3000341070;** **3000355577;** **3000358977**
BO-RF-32-USA RotaFlow Centrifugal Pump with SOFTLINE Coating	701047553	**04037691650326**	3000283239; 3000330438; **3000334430;** **3000344495;** **3000351245**
Manufacturing Dates for All:	December 1, 2022, through **December 4, 2023**		
Distribution Dates for All:	October 10, 2023, through **February 29, 2024**		

Dear Risk Manager,

Maquet Cardiopulmonary GmbH (MCP)/Getinge is notifying customers of additional lots of ROTAFLOW Centrifugal Pumps (RF-32 pumps) that are affected by a voluntary Medical Device Removal (originally initiated on January 8, 2024) due to a potentially compromised sterile barrier. As a result of these added lot numbers, the related manufacturing and distribution date ranges have been updated accordingly. Additionally, the UDI Device Identifiers reported previously had a typographical error. All of these changes are highlighted in **bold** text in the table above.

The company is removing all affected devices, as specified above, from the field.

The RF-32 pumps are intended to maintain blood flow during extracorporeal circulation.

Identification of the issue:

The RF-32 pumps are packaged in sterile bags supplied to MCP/Getinge from its supplier Nelipak. MCP/Getinge initially identified three batches of Nelipak bags that exhibited nonconformities at

their seal, which could potentially compromise the sterile barrier for the RF-32 pumps contained within them. The January 8, 2024 Medical Device Removal was limited to products that contained sterile bags from those three affected supplier batches. MCP/Getinge is now expanding the scope of this Medical Device Removal to include product packaged in two additional batches of Nelipak bags that were identified as nonconforming during further investigation of the issue. Both the originally identified and newly added affected product are listed above.

Risks To Health:

Because the Nelipak bag serves as the primary sterile barrier for the RF-32 pumps, MCP/Getinge's Health Hazard Evaluation (HHE) determined that a breach of the sterile barrier of the RF-32 could expose patients to pathogenic agents. This hazardous situation could result in the following potential harms:

- Inflammation
- Infection
- Sepsis

There have been no adverse events or customer complaints related to the issue described above.

Actions to be taken by the customer:

Our records indicate that you have received RF-32 pumps having one or more of the lot numbers that are affected by this medical device removal (see page 1).

Please examine your inventory immediately to determine if you have any of the RF-32 pumps with the product codes/lot numbers listed in this notice and remove these from use.

If a product is already in use, do not discontinue therapy as the potential risk increases when disconnecting the product during ongoing therapy. Please monitor the patient closely for any signs of infection.

Please immediately quarantine all affected products in your stock and return any unopened/unexpired affected product to MCP/Getinge. Please contact MCP/Getinge Customer Support at (888) 943-8872 (press option 2), Monday through Friday, between the hours of 8:00 a.m. and 6:00 p.m. (Eastern Time Zone) to arrange return of the product and to obtain related shipping instructions. This product is sold in cases of 10 units. Credit will be issued for returned partial cases and unaffected replacement product will be issued for returned full cases.

Whether or not your facility has affected product(s) listed in this notice, and even if your facility has previously provided a response to the earlier January 16, 2024 Medical Device Correction, please complete and sign the attached MEDICAL DEVICE REMOVAL - RESPONSE FORM (page 4 herein) to acknowledge that you have received this notification. Return the completed form to MCP/Getinge by e-mailing a scanned copy to RF32sterility2024.act@getinge.com or by faxing the form to 1 (866) 499-9223.

Please forward this information to all current and potential RF-32 pump users within your hospital / facility.

If you are a distributor who has shipped any affected products to customers, please forward this document to their attention for appropriate action.

Replacement/new products can be ordered as usual.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax using the following:

- **Online**: www.accessdata.fda.gov/scripts/medwatch/
- **Regular Mail**: Download form at www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form
- **Fax**: 1-800-FDA-0178 (1-800-332-0178)

Actions to be taken by Getinge:

Getinge will facilitate the removal of affected products from your facility and provide credit/replacement for your return of these products (see previous section for details). This voluntary removal only affects the products listed on page 1; no other RF-32 products are affected by this voluntary medical device removal.

We apologize for any inconvenience this medical device removal may cause. If you have any questions, please contact your MCP/Getinge representative or call the Maquet/Getinge Customer Support at (888) 943-8872 (press option 2), Monday through Friday, between the hours of 8:00 a.m. and 6:00 p.m. (Eastern Time Zone).

This medical device removal is being made with the knowledge of the U.S. Food and Drug Administration.

Sincerely,

Charles Ryan
Senior Manager, Regulatory Affairs and Field Action Compliance