January 8, 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	4037691530864	3000286570 3000325568
BO-RF-32-USA RotaFlow Centrifugal Pump with SOFTLINE Coating	701047553	4037691650326	3000283239 3000330438
Manufacturing Dates for All:	December 1, 2022, through July 21, 2023		
Distribution Dates for All:	October 10, 2023, through December 15, 2023		

Dear Risk Manager,

Maquet Cardiopulmonary GmbH (MCP)/Getinge is initiating a voluntary Medical Device Removal for certain lots of ROTAFLOW Centrifugal Pumps (RF-32 pumps) due to a potentially compromised sterile barrier.

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. Through internal testing, MCP/Getinge identified three batches of Nelipak bags that exhibit nonconformities at their seal, which could potentially compromise the sterile barrier for the RF-32 pumps contained within them. This Medical Device Removal is limited to products that contain sterile bags from these three affected supplier batches.

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 reported 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 request a return authorization (RMA) number and 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, 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

GETINGE

URGENT: MEDICAL DEVICE - REMOVAL RESPONSE FORM

FSCA 8010762-01/08/2024-001-R

ROTAFLOW Centrifugal Pumps (RF-32 Pumps)

DISTRIBUTION DATES: October 10, 2023, through December 15, 2023

If the affected product has been sold or moved to another facility, please complete the following:

New Facility Name:	
New Facility Address:	
New Facility Contact Name:	
New Facility Phone Number:	

Return the completed form by EMAIL to RF32sterility2024.act@getinge.com

or by FAX to 1 (866) 499-9223