May 19, 2023

# URGENT MEDICAL DEVICE – Removal

## Reference Number: : 8010762-03/27/2023-001-R and 8010762-03/27/2023-002-R

## QUADROX-iD / QUADROX-iR / QUADROX-i Oxygenators and Cardiotomy Reservoirs

| ITEM | ITEM DESCRIPTION | UDI (Single device) |
|---|---|---|
| 701050330 | QUADROX-iD Pediatric- BEQ-HMOD30000-USA | 4037691670164 |
| 701070397 | QUADROX-iD Pediatric- BEQ-HMOD30000-USA | 4058863154435 |
| 701067840 | HMOD 70000-USA/ QUADROX -iD Adult | 4058863019000 |
| 701067859 | BEQ-HMOD70000-USA/ QUADROX -iD | 4058863019024 |
| 701067905 | BEQ-HMO 50000-USA / QUADROX -i Small | 4058863019079 |
| 701067891 | HMO 50000-USA /QUADROX-i Small Adult | 4058863019055 |
| 701067895 | HMO 51000-USA /QUADROX-i Small Adult | 4058863019185 |
| 701067820 | HMO 70000-USA /QUADROX-i Adult | 4058863019147 |
| 701067823 | HMO 71000-USA /QUADROX-i Adult | 4058863017341 |
| 701067829 | BEQ-HMO 71000-USA /QUADROX-i Adult | 4058863017372 |
| 701070412 | HMO 10000-USA /QUADROX -i Neonatal | 4058863154473 |
| 701070416 | HMO 11000-USA /QUADROX -i Neonatal | 4058863154558 |
| 701070384 | HMO 30000-USA /QUADROX-i Pediatric | 4058863153681 |
| 701070388 | HMO 31000-USA /QUADROX-i Pediatric | 4058863154299 |
| 701070441 | VKMO 10000-USA /Venous Hardshell Cardiotomy Reservoir | 4058863153889 |
| 701070445 | VKMO 11000-USA /Venous Hardshell Cardiotomy Reservoir | 4058863153889 |
| 701067936 | BEQ-HMO 51100-USA-QUADROX-iR Small Adult with filter, with BIOLINE Coating | Not Applicable |
| 701067880 | BEQ-HMO 71100-USA-QUADROX-iR Adult with filter, with BIOLINE Coating | 4058863164052 |
| 701067934 | HMO 50100-USA-QUADROX-iR Small Adult without filter, with SOFTLINE Coating | Not Applicable |
| 701067938 | HMO 51100-USA-QUADROX-iR Small Adult with filter, with SOFTLINE Coating | Not Applicable |
| 701067874 | HMO 70100-USA-QUADROX-iR Adult without filter, with SOFTLINE Coating | Not Applicable |
| 701067886 | HMO 71100-USA-QUADROX-iR Adult with filter, with SOFTLINE Coating | Not Applicable |

| | |
|---|---|
| **Affected Lot Numbers:** | **All lots within product expiry** |
| **Manufacturing Dates:** | **April 06, 2020 to December 12, 2022** |
| **Distribution Dates:** | **September 04, 2020 to March 01, 2023** |

Dear Risk Manager or Designee,

Maquet Cardiopulmonary GmbH/Getinge is initiating a voluntary Medical Device Removal for the Cardiotomy Reservoirs (VKMO 10000-USA, VKMO 11000-USA), QUADROX-iD (BEQ-HMOD 30000, HMOD 70000, and BEQ-HMOD 70000), QUADROX-iR (HMO 71100, HMO 70100, BEQ-HMO 71100, HMO 51100, HMO 50100, BEQ-HMO 51100), and QUADROX-, i (HMO 50000, HMO 51000, HMO 70000, HMO 71000, and BEQ_HMO 71000, HMO 10000, HMO 11000, HMO 30000 and HMO 31000) Oxygenators due to a risk of potentially compromised packaging sterility that may result in the risk of infection/harm to the patient. **All lots are being removed**.

The QUADROX oxygenators are blood-gas exchangers with integrated heat exchanger. They are used to oxygenate blood, remove carbon dioxide and adjust blood temperature during cardiopulmonary bypass/open-heart procedures with up to a 6-hour duration of use.

The venous hardshell cardiotomy reservoir is used to collect, store and filter blood in extracorporeal circulation in cardiopulmonary bypass operations on pediatric patients for up to 6 hours. The reservoir can also be employed postoperatively as drainage and autotransfusion reservoir (e.g., for thorax drainage) to return the autologous blood to the patient which was removed from the thorax for the volume exchange.

Affected product is being removed due to the following issues:

1. An accessory may be improperly placed during packaging, causing creases and damage to the accessory's sterile pouch.

2. Product packaging may exhibit holes, cracks, dents, and crushed areas.

3. Product packaging may exhibit small pinholes which may not be visible to the unaided eye.

All three issues may compromise the sterile barrier of the packaging.

Maquet Cardiopulmonary GmbH has not received any reports of complaints or adverse events due to this issue.

**Risk To Health:**
Exposure to a non-sterile or potentially non-sterile medical device may result in the following health hazards: inflammation, infection, sepsis, and ischemia.

**Actions to be taken by the customer:**

- Our records indicate that you have received QUADROX Oxygenators/ Cardiotomy Reservoirs affected by this recall.

- If an affected device is already in use, please use according to normal practices. Monitor the patient for signs and symptoms as listed above under Risk to Health and, if detected, treat according to clinical protocols.

- Please examine your inventory immediately to determine if you have any QUADROX Oxygenators/ Cardiotomy Reservoirs. If you have any affected product, please remove the device from areas of use.

- Please forward this information to all current and potential QUADROX Oxygenator/ Cardiotomy Reservoirs 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.

- If you have un-opened and un-expired QUADROX oxygenators/ Cardiotomy Reservoirs, you are eligible for credit upon return.

- **Product Return:** Please contact Getinge Customer Service at 1-888-943-8872 option 2 between the hours of 6:00 AM and 5:00 PM Pacific Standard Time to request a return authorization (RMA) and shipping instructions to return any affected product.

- **Response Form**: Whether you have affected product or not, please complete and sign the Response Form on pages 4 and 5 and return the completed form to Getinge by e-mailing a scanned copy to QUADROXoxygenator-2023.act@getinge.com or by faxing the form to (877)-502-2246.

**Actions to be taken by Getinge:**

Maquet Cardiopulmonary GmbH is working with all possible urgency on the redesign and revalidation of a packaging solution, which is anticipated to be available by Q4 2023.

This voluntary removal only affects the products referenced on page 1; no other products are affected by this voluntary recall.

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 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

We apologize for any inconvenience this recall may cause. If you have any questions, please contact your Maquet Cardiopulmonary GmbH/Getinge representative Getinge Customer Service at (888) 880-2874, Monday through Friday, between the hours of 6:00 a.m. and 5:00 p.m. (Pacific Standard Time).

This recall is being made with the knowledge of the U.S. Food and Drug Administration.

Sincerely,

**Maryanna Krivak**
Regulatory Affairs Specialist II, Regulatory Affairs and Field Action Compliance

USA Shared Services
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