April 25, 2019

RE: Maquet Cardiopulmonary (MCP) / Getinge Cardiohelp Emergency Drive Recall

To Whom It May Concern,
Cc: Chairman Medical Board and relevant Head-of-Department

We, MCP/Getinge, confirm that none of the affected medical devices included in the below Field Safety Notice - FSN were supplied to and/or shipped to and/or installed in Singapore, therefore, Singapore is not affected by this FSN.

Medical Devices Name	FDA reference number / ECRI reference number
Part: 70104.8002 [redacted]	Z-0986-2019 / A32442

Sincerely,

[redacted]

Marylou Insinga
Senior Specialist, Regulatory Affairs & Field Action Compliance
Maquet/Getinge

[redacted]

Getinge
45 Barbour Pond Drive
Wayne, NJ 07470 USA
www.getinge.com

[Month DD, YYYY] via FedEx

URGENT MEDICAL DEVICE RECALL – CORRECTION

CARDIOHELP EMERGENCY DRIVE

Product Code/Part Number:	**70104.8002 Emergency Drive**
Distributed Affected Serial Numbers:	[redacted]
Manufacturing Dates:	**August 08, 2011 to May 20, 2016**
Distribution Dates:	**November 28, 2018 to February 7, 2019**

PLEASE FORWARD THIS INFORMATION TO ALL CURRENT AND POTENTIAL CARDIOHELP-i USERS WITHIN YOUR HOSPITAL / FACILITY.

Dear Risk Manager,

Maquet Cardiopulmonary (MCP)/Getinge performed a voluntary Medical Device Correction for the Cardiohelp Emergency Drive an accessory (ref. Figure 1, below) to the Cardiohelp-i system located at your facility. The gearwheel within the Cardiohelp Emergency Drive may have been incorrectly re-assembled after servicing. The Cardiohelp Emergency Drive at your facility was inspected for possible incorrect gear assembly. In order to ensure the continued use of the Cardiohelp-i system, if the issue was identified, the Emergency Drive was removed and replaced with a loaner Emergency Drive.

Figure 1: Emergency drive mounted on Cardiohelp-i

Identification of the issue:

If the Cardiohelp-i system should fail, the Emergency Drive can be used to keep the pump rotating. If the gearwheel is assembled incorrectly the Cardiohelp-i system will not perform as intended and patient stabilization may not be able to be achieved.

The issue was identified during a 2 year preventive maintenance of Cardiohelp Emergency Drives performed at a U.S. Getinge repair depot.

The issue was isolated to a newly trained Getinge repair technician. A total of 10 units (7 of these units were distributed to customers) had been serviced by this technician since November 2018. All Emergency Drives serviced by this technician were inspected at your facility and if the Emergency Drive was found to be incorrectly assembled it was removed and replaced.

It is important to note, there have been no adverse events or deaths attributed to this issue.

Actions to be taken:

Our records indicate that you have received one or more Cardiohelp- i systems having an Emergency Drive accessory serial number affected by this recall.

The Emergency Drive at your facility has already been inspected and replaced with a loaner Emergency Drive if found to be affected. Affected Emergency Drives were returned to Getinge for servicing. Upon servicing, a service technician will return the Emergency Drive back to your facility.

Please complete and sign the attached MEDICAL DEVICE RECALL – CORRECTION RESPONSE FORM (page 3) to acknowledge that you have received this notification. Return the completed form to Maquet/Getinge by e-mailing a scanned copy to Marylou.insinga@getinge.com or by faxing the form to 1-973-807-9290.

This Medical Device Correction only affects the products listed on page 1; no other products are affected by this Medical Device Correction.

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

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.fda.gov/medwatch/report.htm
- **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 (MCP)/Getinge representative or call the Maquet Cardiopulmonary (MCP)/Getinge Customer Support at +1 (888) 627-8383 (press option 2, then option 2), Monday through Friday, between the hours of 8:00 a.m. and 6:00 p.m. (Eastern Time Zone).

This Medical Device Correction is being made with the knowledge of the U.S. Food and Drug Administration.

Sincerely,

[redacted]

Marylou Insinga
Senior Specialist, Regulatory Affairs and Field Action Compliance

Getinge
45 Barbour Pond Drive
Wayne, NJ 07470 USA
www.getinge.com

[Month DD, YYYY]

URGENT: MEDICAL DEVICE RECALL –CORRECTION RESPONSE FORM

CARDIOHELP EMERGENCY DRIVE
Product Code/Part Number: 70104.8002
FAX BACK TO: 1-973-807-9290 or EMAIL TO: marylou.insinga@getinge.com

DISTRIBUTION DATES: November 28, 2018 to February 7, 2019

ADD ACCOUNT#
[FACILITY NAME
STREET ADDRESS
CITY, STATE, ZIP CODE]

Please acknowledge that you have read and understand this Medical Device Correction Notice for the Cardiohelp Emergency Drive. Please ensure that all users of Cardiohelp-i at this facility have been notified accordingly.

Please provide the required information and signature below.

Facility Representative Information:

Signature:_____ Date:_____

Name:_____ Phone:_____

Title:_____ Department:_____

Hospital Name:_____

Address, City and State:_____

Return the completed form by FAX to 1-973-807-9290 or by EMAIL to marylou.insinga@getinge.com