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Class 2 Device Recall GETINGE Y SENSOR Module, SERVOU, SERVON



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Class 2 Device Recall GETINGE Y SENSOR Module, SERVOU, SERVON



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Date Initiated by Firm	June 30, 2026
Date Posted	August 14, 2026
Recall Status ¹	Open ³ , Classified
Recall Number	Z-2963-2026
Recall Event ID	99439 ²³
510(K)Number	K201874 ²⁴
Product Classification	Ventilator, continuous, facility use ²⁵ - Product Code CBK ²⁶
Product	GETINGE Y SENSOR Module, SERVO-U, SERVO-N, Model Number 6693662; part of the SERVO-U/-N continuous ventilator system, for facility use. Maquet Critical Care AB, is a subsidiary of Getinge.
Code Information	DUI/DI 07325710000304, Serial/Lot Numbers: 21049, 21088, 21089, 21093, 21100, 21103, 21108, 21114, 21115.
FEI Number	3002808128
Recalling Firm/ Manufacturer	Maquet Critical Care AB Rontgenvagen 2 Solna Sweden
Manufacturer Reason for Recall	The module did not undergo electrical safety tests and functional tests during production.
FDA Determined Cause ²	Under Investigation by firm
Action	Getinge issued an URGENT MEDICAL DEVICE CORRECTION notice was issued to its consignees on 7/9/2026 via FedEx. The notice explained the issue, potential risk to health, and requested the following: "Prior to the replacement, Getinge requests that you take the following actions: 1. Ensure all affected product in your inventory has been identified. 2. Please ensure this message is forwarded to any individuals that need notification within your organization or any organization where the affected devices have been transferred. 3. Contact Technical Service if you have questions at 888-943-8872 (888 9GETUSA), Option 4, Monday through Friday, between the hours of 8:00 a.m. and 6:00 p.m. (Eastern Time Zone). 4. Complete and return the enclosed response form to Getinge by e-mailing a copy to recallresponses.qrc@getinge.com. For questions regarding this communication, please contact contact Technical Service if you have any questions at 888-943-8872 (888 9GETUSA), Option 4, Monday through Friday, between the hours of 8:00 a.m. and 6:00 p.m. (Eastern Time Zone).
Quantity in Commerce	9 units
Distribution	US Nationwide distribution in the states of CA, GA, MN, NY.
Total Product Life Cycle	TPLC Device Report ²⁷

¹ A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about [medical device recalls](#)²⁸.

² Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

³ The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database

[510\(K\)s with Product Code = CBK](#)²⁹

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