March 2026

URGENT MEDICAL DEVICE CORRECTION
Getinge Steam Sterilizers

Model Number	Serial Numbers	Distribution Dates
See Appendix A	All Serial Numbers	Prior to 04 September 2019

Dear Customer,

Getinge Sterilization AB has issued this notification to inform you about a safety issue related to the Getinge Steam Sterilizers as listed in Appendix A.

Issue Description

Getinge Sterilization AB received a report of a user injury involving the autoclave door. The sterilization technician activated the door lock while a basket was obstructing the door's movement. Rather than reopening the door and repositioning the basket, the technician attempted to manually adjust the basket while the door was closing. When the basket became dislodged, the door closed and resulted in a serious crushing injury to the technician's hand.

During further investigation, a second complaint involving a similar device was also identified.

Risks to Health

The identified risk involves the potential for pinch or crush injuries to fingers if the door is interfered with during closing. Through March 2026, Getinge Sterilization AB has received two complaints related to this risk.

Issue Investigation

Getinge Sterilization AB has completed an investigation which showed that the devices were functioning as intended. The investigation concluded that the issues occurred due to a user error rather than a device malfunction. This investigation into the two complaints found that the following combination of non-device factors resulted in the issue:

- A loading basket was incorrectly positioned inside the sterilizer.
- The door closing process was not monitored.
- The loading basket became stuck during door closure.
- When the basket became stuck, the emergency stop was not used.
- The machine operator reached into the active machine to remove the stuck basket and subsequently got the hand pinched between the door and the doorframe.

Customer Actions

Our records indicate that you have received one or more of the serial numbers that are affected by this issue. As a result, we request that you take the following actions:

1. Continue operating the affected sterilizers in accordance with the Instructions for Use and all safety precautions described in the User Manual.
2. **Ensure that all relevant personnel are informed of and adhere to the following safety measures:**
    - **The emergency stop button must be used prior to attempting to reposition any load or obstruction that may interfere with door movement.**
    - **Personnel must not reach into the chamber when the door is stuck, obstructed, or in motion.**
3. Please ensure this notice is distributed to all relevant personnel within your organization and to any organization to which affected devices may have been transferred.
4. Please complete and sign the attached response form to acknowledge receipt of this notification.

Additional Information

Getinge is communicating this information to the appropriate regulatory agencies.

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 regret any inconvenience this may cause. We are committed to user safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Getinge representative.

Sincerely,

Daniel Berntsson
Electronically signed by: Daniel Berntsson
Reason: I approve this document.
Date: Mar 24, 2026 15:33:05 GMT+1

Daniel Bernstsson
Quality Director
Getinge Sterilization AB

Rob Slobbe
Electronically signed by: Rob Slobbe
Reason: I approve this document.
Date: Mar 24, 2026 15:29:16 GMT +1

Rob Slobbe
Vice President Quality Life Science
Getinge

Appendix A: Affected Model Numbers

GE 6610 AR-1
GE 669 AC-1
GE 6610 AR-2
GE 666 AC-1
GE 61212 AR-1
GE 6617 AR-1
GE 6610 DRB-2
GE 666 EC-1
GE 6613 EC-1
GE 666 ER-1
GE 6610 ER-1
GE 6617 ER-1
GE 6610 AC-1
GEL 6613 AR-1
GE 6610 EMC-2
GE 6610 ARB-2
GE 6610 ARB-2 SPF Vä
GE 6612 ARB-2 SPF
GE 6610AR-1
GE 6610 ARCB-2
GE 6610 ARB-2 SPF
GE 6610 AR-1 VÄNSTER
GE 6610 AR-2 SPF
GE 669 ARB-2 SPF
GE 669 AR-1
GE 669 ARB-2
GE 6612 ARB-2
GE 6617 ARB-2
GE 6613 ARB-2
GE 6612 AR-1
GE 6612 AR-2
GE 669AR-1

GE 61616 AR-1
GE 6610 EC-1
GE 6613 AR-1
GE 6613 ERB-2
GE 6613 ARCC-2
GE 6612 AC-1
GE 6610 ARC-1
GE 6610 ER-2
GE 6813 ARC-2
GE 666 AMC-2
GE 6610 ERC-1
GE 6613 ER-2
GE 6610 ERB-2
GE 61214 AR-1
GE 6617 ARB-1
GE 6610 DR-1
GE 6910 AR-1
GE 6613 ARC-2
GE 6613 AC-1
GEL 6613 AC-1
GE 6613 DR-1
GEL 6610 AR-1
GE 6913 AC-1
GE 6610 ARC-2
GE 6613 ERC-2
GEL 6610 EC-1
GE 6913 ERC-2
GE 6910 ER-2
GE 6610 AMC-2
GE 6913 EC-1
GE 6613 AMC-2
GE 6910 ER-1

GE 6610AC-1
GE 6610 AMB-2
GE 6610 DM-1
GE6610 DM-1
GE6610 AR-1
GEL 6610 AC-1
GE 666 AR-1
GE 6910 AC-1
GE 666AR-1
GE 6913 DC-1
GEL 6613 EC-1
GEL 6610 DR-1
GE 6617 AMC-2
GE 6613 ARB-1
GE 666 ARB-1
GE 6613 DC-1
GE6610 ER-1
GE 6610 DMC-2
GE 666 EMC-2
GE 6610 DC-1
GE 666AMB-1
GE 6913 ARB-2
GE 6610 EMB-2
GE 6610 DR-2
GE 6617 ARCB-2
GEL 6610 ARC-2
GE 6915 ARB-2
GE 6613 EMB-2
GE 6610 ARB-1
GE 669AC-1
GE 6610 AMC-2 (ARC(C)-2)
GE 6913 ARC-1

GEC 6613 AM-2
GEB 6913 ARB-2
GEB 6610 AMBS-2
GEB 6610 AMBS_2
GEB 6610 ARBS-2
GEB 6910 ARB-2
GEB 6915 ARB-2
GEB 6610 ARB-2
GEB 6608 AMBS-2
GEB 6613 ERB-2
GEB 6613 ARB-2
GEV 6614 AR-2
GE 6614 AR-2
GEV 669 AC-1
GEV 6610 AC-1
GEV 6610 ER-1
GEV 6610 EC-1
GEV 6613 AR-1
GEV 6610 DR-1
HS 6613 AM-2
GE 6612 AC - 1
GE 6610 AR - 1
GE 6613 ERB-1
GEB 6608 EMBS-2
GE 6612 EC-1
GE 672*920*1550-1
GE 672*920*1000-1
GE 672*920*1350-2
GEV6612AC-1
GE 6612AR-2
GE510AR-1
GE 6610AR-2