

Field Safety Corrective Action
Getinge Steam Sterilizers
Reference Number: 1480818

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:**
 - o **The emergency stop button must be used prior to attempting to reposition any load or obstruction that may interfere with door movement.**
 - o **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.

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 Bernstsson
Quality Director
Getinge Sterilization AB

Rob Slobbe
Vice President Quality Life Science
Getinge

Appendix A: Affected Model Numbers

GE 666 ERC-2	GE 6610 AC-2	GE 6610 ER-2	GE 6613 AM-2
GE 510 AC-1	GE 6610 AC-2 SL400	GE 6610 ERB-1	GE 6613 AMB-2
GE 5510 AC-1	GE 6610 AM-1	GE 6610 ERB-2	GE 6613 AMC-2
GE 5510 EC-1	GE 6610 AM-2	GE 6610 ERBB-2	GE 6613 AR-1
GE 5510 ER-1	GE 6610 AMB-2	GE 6610 ERC-1	GE 6613 AR-2
GE 5510 EV-1	GE 6610 AMC-2	GE 6610 ERC-2	GE 6613 ARB-1
GE 61019 AR-2	GE 6610 AR - 1	GE 6610AC-1	GE 6613 ARB-2
GE 6109 AR-2	GE 6610 AR-1	GE 6610AR-1	GE 6613 ARBB-2
GE 61212 AR-1	GE 6610 AR-2	GE 6610AR-2	GE 6613 ARBC-2
GE 61214 AR-1	GE 6610 AR-2 SPF	GE 6610ERC-2	GE 6613 ARC-1
GE 61616 AR-1	GE 6610 ARB-1	GE 6612 AR-2	GE 6613 ARC-2
GE 66*920*1250-1	GE 6610 ARB-2	GE 6612 AC-1	GE 6613 ARCB-2
GE 66*920*1540-1 V	GE 6610 ARB-2 SPF	GE 6612 AR-1	GE 6613 ARCC-2
GE 660 EC-1	GE 6610 ARBB-2	GE 6612 AR-2	GE 6613 DC-1
GE 660*1050*1700-1	GE 6610 ARC-1	GE 6612 AR-2 SPF	GE 6613 DMC-2
GE 660*920*1000	GE 6610 ARC-2	GE 6612 ARB-2	GE 6613 DR-1
GE 660*920*1000 AR-1	GE 6610 ARCB-2	GE 6612 ARB-2 SPF	GE 6613 DRB-2
GE 660*920*1000-1	GE 6610 DC-1	GE 6612 ARC-2	GE 6613 DRC-2
GE 660*920*1250 EU	GE 6610 DM-1	GE 6612 EC-1	GE 6613 EC-1
GE 660*920*1250-1	GE 6610 DM-2	GE 6612 ECK-1	GE 6613 EERBC-2
GE 660*920*1250-2	GE 6610 DMC-2	GE 6612 ECK-2	GE 6613 EMB-2
GE 660*920*1350-1	GE 6610 DR-1	GE 6612 ER-1	GE 6613 EMC-2
GE 660*920*1350-2	GE 6610 DR-2	GE 6612 ER-2	GE 6613 EMKB-2
GE 660*920*1540-1	GE 6610 DRB-2	GE 6612 ERC-2	GE 6613 ER-1
GE 660*920*1540-2	GE 6610 DRC - 2	GE 6612 ERCK-2	GE 6613 ER-2
GE 660*920-1	GE 6610 DRC-2	GE 6612 ERK-1	GE 6613 ERB-1
GE 660*920-2	GE 6610 EC-1	GE 6612 ERK-2	GE 6613 ERB-2
GE 660Z ARC-2	GE 6610 EM-2	GE 6612 RAR-1	GE 6613 ERBC-2
GE 660X920X1350-1	GE 6610 EMB-2	GE 6612 ST AR-2	GE 6613 ERC-2
GE 6610 AC-1	GE 6610 EMC-2	GE 6612AR-2	GE 6613 AMC-2
	GE 6610 ER-1	GE 6613 AC-1	GE 6614 AR-2

GE 6616 AR-2	GE 6620 ERC-2	GE 669 AAR-2	GE 6910 ER-2
GE 6617 AC-1	GE 666 AC-1	GE 669 AC-1	GE 6913 AC-1
GE 6617 AM-2	GE 666 AC-2	GE 669 AR-1	GE 6913 AR-1
GE 6617 AMB-2	GE 666 AMC-2	GE 669 AR-2	GE 6913 ARB-2
GE 6617 AMC-2	GE 666 AR-1	GE 669 ARB-2	GE 6913 ARC-1
GE 6617 AR-1	GE 666 AR-2	GE 669 ARB-2 SPF	GE 6913 ARC-2
GE 6617 AR-2	GE 666 AR-2 SPF	GE 669 ARC-1	GE 6913 DC-1
GE 6617 ARB-1	GE 666 ARB-1	GE 669 ARC-2	GE 6913 EC-1
GE 6617 ARB-2	GE 666 ARB-2	GE 669 C-1	GE 6913 ERC-2
GE 6617 ARBC-2	GE 666 ARBC-2	GE 669 EC-1	GE 6915 ARB-2
GE 6617 ARC-2	GE 666 ARC-2	GE 669 EC-2	GEA 6612 AR-2
GE 6617 ARCB-2	GE 666 ARC-2 SPF	GE 669 ECK-1	GEA 6617 AR-2
GE 6617 DC-1	GE 666 ARCK-2	GE 669 ER-1	GEA 669 AR-2
GE 6617 DMB-2	GE 666 ARK-2	GE 669 ER-2	GEB 6608 AMBS-2
GE 6617 DRC-2	GE 666 DC-1	GE 669 ERB-2	GEB 6608 EMBS-2
GE 6617 EC-1	GE 666 DR-1	GE 669 ERC-2	GEB 6610 AMB-2
GE 6617 EC-2	GE 666 DRC-2	GE 669 ERCK-2	GEB 6610 AMBS-2
GE 6617 EMC-2	GE 666 EC-1	GE 669 ERK-2	GEB 6610 AMBS_2
GE 6617 ER-1	GE 666 EC-2	GE 669 ST AC-1	GEB 6610 ARB-2
GE 6617 ER-2	GE 666 EM-2	GE 6718 ARB-2	GEB 6610 ARBS-2
GE 6617 ERB-1	GE 666 EMB-2	GE 672*1050*1300-2	GEB 6610 EMB-2
GE 6617 ERB-2	GE 666 EMC-2	GE 672*920*1000-1	GEB 6610 ERB-2
GE 6617 ERC-2	GE 666 ER-1	GE 672*920*1000-1L	GEB 6613 AMB-2
GE 6617 ERK-1	GE 666 ER-2	GE 672*920*1000-2	GEB 6613 ARB-2
GE 6617 ERK-2	GE 666 ERB-2	GE 672*920*1350-2	GEB 6613 EMB-2
GE 6618 AR-2	GE 666 ERC-2	GE 672*920*1550-1	GEB 6613 ERB-2
GE 6618 ER-2	GE 666 ERK-1	GE 6813 ARC-2	GEB 6613 ERBS-2
GE 6620 AMC-2	GE 666 ERK-2	GE 6910 AC-1	GEB 6617 ERB-2
GE 6620 AR-2	GE 666AMB-1	GE 6910 AR-1	GEB 6910 ARB-2
GE 6620 ARC-2	GE 666AR-1	GE 6910 ARB-2	GEB 6910 ERB-2
GE 6620 EM-2	GE 666ARC-2	GE 6910 ARC-2	GEB 6913 ARB-2
GE 6620 ER-2	GE 667 AR-2	GE 6910 ER-1	GEB 6915 ARB-2

GEB 6915 EMB-2	GEC 6617ER -2	GEL 6610 ER-2	GEL 666 EMC-2
GEB 6915 ERB-2	GEC 669 AC-1	GEL 6610 ERC-1	GEL 666 ER-1
GEC 606 AR-1	GEC 669 AR-1	GEL 6610 ERC-2	GEL 666 ERC-2
GEC 61013 ARC-2	GEC 669 AR-2	GEL 6610-2	GEL 679 EC-1
GEC 6610 ARB-2	GEC 669 EC-1	GEL 6613 AC-1	GEV 506 EC-1
GEC 6610 ARC-2	GEC 669 ER-2	GEL 6613 AC-2	GEV 6012 AR-1
GEC 6610 EC-1	GEC 669 ERC-2	GEL 6613 AM-2	GEV 6012 AR-2
GEC 6610 EM-2	GECA 6617 AC-1	GEL 6613 AMC-2	GEV 6012 AR-2 SPF
GEC 6610 EMC-2	GEE 6612 AR 1	GEL 6613 AR-1	GEV 6012 ER-1
GEC 6610 ER-2	GEE 6612 AR-1	GEL 6613 AR-2	GEV 61210 AR-2 SPF
GEC 6610 ERC-2	GEE 6612 ERC-2	GEL 6613 ARC-2	GEV 660*920*1350 AR-1
GEC 6612 AC-1	GEE 6613 EC-1	GEL 6613 EC-1	GEV 660*920*1350 AR-2
GEC 6612 AR-1	GEE 6617 AR-1	GEL 6613 EM-2	GEV 660*920*1540-2
GEC 6612 AR-2	GEE 6617 AR-2	GEL 6613 EMC-2	GEV 6610 AC-1
GEC 6612 EC-1	GEE 669 AR-1	GEL 6613 ER-1	GEV 6610 AR-1
GEC 6612 ER-2	GEE 669 AR-2	GEL 6613 ER-2	GEV 6610 AR-2
GEC 6612 ERC-2	GEE 669 EC-1	GEL 6613 ERC-1	GEV 6610 ARB-2
GEC 6612ER-2	GEE 669 ER-1	GEL 6613 ERC-2	GEV 6610 ARC-1
GEC 6613 AC-1	GEL 6610 ER-1	GEL 6617 AC-1	GEV 6610 ARC-2
GEC 6613 AM-2	GEL 6610 AC-1	GEL 6617 AR-1	GEV 6610 DC-1
GEC 6613 AR-2	GEL 6610 AR-1	GEL 6617 EC-1	GEV 6610 DMC-2
GEC 6613 ARB-2	GEL 6610 AR-2	GEL 6617 EM-2	GEV 6610 DR-1
GEC 6613 ARCB-2	GEL 6610 ARC-2	GEL 6617 ER-2	GEV 6610 DRB-2
GEC 6613 DRC-2	GEL 6610 DC-1	GEL 6617 ERC-2	GEV 6610 DRC-2
GEC 6613 EC-1	GEL 6610 DR-1	GEL 6620 ER-2	GEV 6610 EC-1
GEC 6613 ERC-2	GEL 6610 DRB-1525	GEL 666 AR-1	GEV 6610 EMB-2
GEC 6615 DRC-2	GEL 6610 EC-1	GEL 666 AC-1	GEV 6610 EMC-2
GEC 6617 AC-1	GEL 6610 EM-1	GEL 666 AR-1	GEV 6610 ER-1
GEC 6617 AR-1	GEL 6610 EM-2	GEL 666 ARC-2	GEV 6610 ERB-2
GEC 6617 AR-2	GEL 6610 EMB-2	GEL 666 DC-1	GEV 6610 ERC-1
GEC 6617 ER-1	GEL 6610 EMC-2	GEL 666 EC-1	GEV 6612 AR - 2
GEC 6617 ER-2	GEL 6610 ER-1	GEL 666 EMB-2	

GEV 6612 AR-1	GEV 6615 ARC-2	GEVC 6712AC- 1	HS 6606 DR-2
GEV 6612 AR-2	GEV 6617 ARC-2	GSS-L 6710 AC-1	HS 6606 EC-1
GEV 6612 AR-2 SPF	GEV 6617 DR-1	HS 5510 AC-1	HS 6606 EC-1 LTSF
GEV 6612 ARB-2	GEV 6620 ER-1	HS 5510 AM-2	HS 6606 EM-2
GEV 6612 ARC-1	GEV 666 AC-1	HS 5510 AMC-2	HS 6606 EM-2 LTSF
GEV 6612 ARC-2	GEV 666 EC - 1	HS 5510 AR-1	HS 6606 EMB-2
GEV 6612 EC-1	GEV 666 EC-1	HS 5510 DR-1	HS 6606 EMC-2
GEV 6612 ER-1	GEV 669 AC-1	HS 5510 DR-2	HS 6606 EN ER-1
GEV 6612 ER-2	GEV 669 AR-1	HS 5510 EC-1	HS 6606 ER-1
GEV 6612 ER-2 SPF	GEV 669 AR-1 SPF	HS 5510 EC-1 LAB	HS 6606 ER-1 LAB
GEV 6612 ERC-1	GEV 669 AR-2	HS 5510 EC-2	HS 6606 ER-1 LTSF
GEV 6612 ERC-2	GEV 669 AR-2 SPF	HS 5510 EM-2	HS 6606 ER-2
GEV 6612AR-2	GEV 669 ARC-2	HS 5510 EMB-2	HS 6606 ERB-2
GEV 6613 AC-1	GEV 669 EC-1	HS 5510 EMC-2	HS 6606 ERC-2
GEV 6613 AR-1	GEV 669 ER-2	HS 5510 ER-1	HS 6606 ERK-2
GEV 6613 AR-2	GEV 669 ERC-2	HS 5510 ER-2	HS 6606 LAB AR-2 SPFA
GEV 6613 AR-2 SPF	GEV 669 ERC-2 SPF-B	HS 5510 ERC-2	HS 6606 LAB ARB-2
GEV 6613 ARB-1	GEV 669 ERK-1	HS 5510 LAB EC-1	HS 6606 LAB EC-1
GEV 6613 ARB-2	GEV 6713 AR-1	HS 5510 LAB EMB-2	HS 6606 LAB ERB-2
GEV 6613 ARBB-2	GEV TS 121675 AR-2	HS 5510-EC-1	HS 6606 LAB ERB-2 SPFB
GEV 6613 ARC-1	GEVA 6612 AR-1	HS 5510LAB DC-1	HS 6606 LAB EM-2
GEV 6613 ARC-2	GEVA 669 ECK-2	HS 5510LAB EC-1	HS 6610 ER-1
GEV 6613 EC-1	GEVC 6012 AR-1	HS 5510R ER-1	HS 6610 ER-2
GEV 6613 EMC-2	GEVC 6012 AR-2	HS 5513 AMB-2	HS 6610 AC-1
GEV 6613 ER-1	GEVC 6610 AR-1	HS 5513 EM-2	HS 6610 AC-1 LAB
GEV 6613 ER-2	GEVC 6612 AR-2	HS 6606 ER-2	HS 6610 AC-2
GEV 6613 ERB-2	GEVC 6613 ARB-1	HS 6606 AC-1	HS 6610 AM-2
GEV 6613 ERC-2	GEVC 669 AC-1	HS 6606 AC-1 LAB	HS 6610 AM-2 LTSF
GEV 6613 ERCB-2	GEVC 669 AR-1	HS 6606 AR-1	HS 6610 AMC-2
GEV 6613-AR-1	GEVC 669 ER-1	HS 6606 AR-2	HS 6610 AR-1
GEV 6614 AR-2	GEVC 6712 AC-1	HS 6606 AR-2 LTSF	HS 6610 AR-1 LTSF
GEV 6615 ARB-2	GEVC 6712 AR-1	HS 6606 DC-1	

HS 6610 AR-1 LTSF	HS 6610 ERC-2	HS 6610T AR-2	HS 6613 DR-2
HS 6610 AR-2	HS 6610 ERK-2	HS 6610T DR-1	HS 6613 DR-2 LTSF
HS 6610 AR-2 LTSF	HS 6610 LAB AC-1	HS 6610T DR-1 LTSF	HS 6613 DRB-2
HS 6610 AR1	HS 6610 LAB AM-2	HS 6610T DR-2	HS 6613 EC-1
HS 6610 ARB-2	HS 6610 LAB AR-1	HS 6610T DR-2 LTSF	HS 6613 EC-1 LTSF
HS 6610 ARB-2 LAB	HS 6610 LAB ARB-2	HS 6610T EC-1	HS 6613 EM -2
SPFB			
HS 6610 ARC-2	HS 6610 LAB ARB-2 SPFA	HS 6610T EC-1 LTSF	HS 6613 EM-2
HS 6610 DC-1	HS 6610 LAB EC-1	HS 6610T EM-2	HS 6613 EM-2 LTSF
HS 6610 DM-2	HS 6610 LAB EMB-2 SPFA	HS 6610T EM-2 LTSF	HS 6613 EMC-2
HS 6610 DMB-2	HS 6610 LAB ER-1	HS 6610T ER-1	HS 6613 ER-1
HS 6610 DR-1	HS 6610 LAB ER-2	HS 6610T ER-1 LTSF	HS 6613 ER-1 LTSF
HS 6610 DR-1 LTSF	HS 6610 LAB ERB SPF B ER-2	HS 6610T ER-2	HS 6613 ER-2
HS 6610 DR-2	HS 6610 LAB ERB-2 SPFA	HS 6610T ER-2 LTSF	HS 6613 ER-2 LTSF
HS 6610 DR-2 LTSF	HS 6610 LAB ERB-2 SPFA	HS 6613 AR-2	HS 6613 ER-2
HS 6610 EC-1	HS 6610 LAB ERB-2 SPFB	HS 6613 ER-2	HS 6613 ER2 LTSF
HS 6610 EC-1 LTSF	HS 6610 LAB ERB-2 SPFB	HS 6613 AC-1	HS 6613 ERB-2
HS 6610 EC-2	HS 6610 N EM-2	HS 6613 AC-1 LTSF	HS 6613 ERC-2
HS 6610 EC-2 LTSF	HS 6610 T DR-1	HS 6613 AM-2	HS 6613 ERK-2
HS 6610 ECK-1	HS 6610 TER-2	HS 6613 AM-2 LTSF	HS 6613 ERK-2 LTSF
HS 6610 EM-2	HS 6610-2	HS 6613 AM-2 SPFB	HS 6613 LAB ARB-2 SPFA
HS 6610 EM-2 LTSF	HS 6610ARB-2LAB	HS 6613 AR-1	HS 6613 LAB EC-1
HS 6610 EMB-2	HS 6610EC-1	HS 6613 AR-1 LTSF	HS 6613 LAB ERB-2 SPFA
HS 6610 EMC-2	HS 6610EM-2	HS 6613 AR-2	HS 6613 N EM-2
HS 6610 ER-1	HS 6610ER-2	HS 6613 AR-2 LAB	HS 6613 T DR-2
HS 6610 ER-1 LAB	HS 6610ER-2 LTSF	HS 6613 AR-2 LTSF	HS 6613 TER-2
HS 6610 ER-1 LTSF	HS 6610N AM-2	HS 6613 AR2	HS 6613-2 LTSF
HS 6610 ER-2	HS 6610N EC-1	HS 6613 ARB-2	HS 6613N EM-2
HS 6610 ER-2 LTSF	HS 6610N EM-2	HS 6613 ARB-2 LAB	HS 6613N AM-2
HS 6610 ER-2 LTSF	HS 6610R ER-1 LTSF	HS 6613 ARC-2	HS 6613N DM-2
HS 6610 ERB-2	HS 6610T ER-2 LTSF	HS 6613 DM-2	HS 6613N EC-1
HS 6610 ERB-2 LAB	HS 6610T AR-1	HS 6613 DM2	HS 6613N ECK-1

HS 6613N EM-2	HS 6613T ER-2 LTSF	HS 6617 ERK-2	HS 661T DR-2
HS 6613N ER-2	HS 6613T LTSF	HS 6617 LAB AR-1	HS 6620 AM-2
HS 6613T DR-2	HS 6616 ER-2	HS 6617 LAB ARB-2 SPFA	HS 6620 AMC-2
HS 6613T ER-2	HS 6617 AR-2	HS 6617 LAB ARB-2 SPFB	HS 6620 AR-1
HS 6613T AR-1	HS 6617 AC-1	HS 6617 LAB ER-2	HS 6620 AR-2
HS 6613T AR-2	HS 6617 AM-2	HS 6617 LAB ER-2 SPFB	HS 6620 AR2
HS 6613T DM-2	HS 6617 AMC-2	HS 6617 LAB ERB-2 SPFB	HS 6620 DM-2
HS 6613T DR-1	HS 6617 AR-1	HS 6617-LAB ARB-2	HS 6620 DR-2
HS 6613T DR-1 LTSF	HS 6617 AR-2	HS 6617T AR-2	HS 6620 EC-1
HS 6613T DR-2	HS 6617 AR-2 LTSF	HS 6617T ER-2	HS 6620 EDR-2
HS 6613T DR-2 LTSF	HS 6617 DM-2	HS 6617T AR-2	HS 6620 EM-2
HS 6613T DR-2 LTSF	HS 6617 DR-2	HS 6617T ER-2	HS 6620 EMC-2
HS 6613T EC-1	HS 6617 EC-1	HS 6617T AR-2	HS 6620 ER-1
HS 6613T EC-1 LTSF	HS 6617 EC-2	HS 6617T DR-2	HS 6620 ER-2
HS 6613T EM-2	HS 6617 EM-2	HS 6617T EM-2	HS 6620LAB ER-2 SPFB
HS 6613T ER-1	HS 6617 EMC-2	HS 6617T ER- 2	HS 666 EM-2
HS 6613T ER-1 LTSF	HS 6617 ER-1	HS 6617T ER-2	HS6606 EC-1
HS 6613T ER-2	HS 6617 ER-2	HS 661N EM-2	HS6620 AR
HS 6613T ER-2 LTSF	HS 6617 ERB-2		