

URGENT – FIELD SAFETY NOTICE

GETINGE Drying Cabinet S-363
Field Action 1490032

Date:	July 2026
Product Issue:	The door on the drying cabinet S-363 fell off
Affected Product:	All Getinge Drying Cabinet of model number S-363, manufactured until 22 August 2025 – has been identified as affected by this FSCA. The units in the below list of affected serial numbers have been identified to be affected for your market.
UDI DI	Basic UDI-DI: 7340153700017W
SRN	SE-MF-000001012
Resolution:	Getinge propose to inspect the devices by checking the hinges and replace any worn out bushings. Preventive Maintenance (PM) is also updated to be included in the PM with a recommendation to check the hinges yearly to make sure all devices present in the market are working effectively and safely. Additionally, the User Manual with the updated PM, will be provided to the customers, either digitally or as a paper copy.
Affected Serial Nos.:	Affected serial numbers for your market can be found below in Appendix A.

Dear Customer:

Our records indicate that you bought one or more devices of Getinge Drying Cabinet S-363 with the serial number(s) listed below.

We have received complaints that the door hinges on the Getinge Drying Cabinet have in some cases come loose, and the door can potentially fall off.

We have over the last 7 years received 10 complaints in total whereof one reportable complaint where the issue resulted in a broken toe.

This letter is to inform you of a corrective action that will be performed to prevent a possible hazard to the user where a door potentially can fall off which can result in an injury for the user. There is no risk for patients.

This potential for malfunction is caused by the device after being used for some time, can loosen the grip of the screws in the hinges, which subsequently contribute to the hinges coming loose.

Tests representing 1 year of use, show no signs of screw loosening, however, the exact time to potential loosening cannot be determined. Therefore, a “period of use” can be defined as a minimum of one year under normal operating conditions.

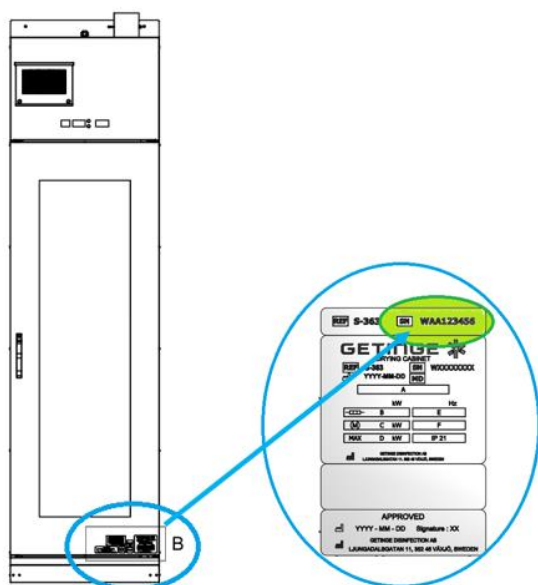
The device is still in production and we have implemented a check point for tightening of the hinge screws with torque, in the manufacturing process. The Preventive Maintenance is also updated with recommendation to inspect the hinges yearly. This FSCA will be performed by checking the hinges according to the updated Preventive Maintenance and replacing the hinge bushings if they are worn out.

The issue we found can cause the door to fall off. This can cause a possible hazard where a person can be exposed to the falling door and potentially cause injury. From our investigation, which includes our evaluation of worst-case scenarios, it was concluded that there is only a remote chance that the problem may cause injury, however it is possible.

Actions to be taken by the customer

1. Please make sure that all users of the Getinge Drying Cabinet S-363 are made aware of this Field Safety Notice and all listed devices at your facility are available to be inspected by a Getinge service technician.
2. Verify the listed serial number and complete and sign the enclosed Customer Response Form, Appendix A below, and return this form to your local Getinge office. Please look at Appendix A for contact information.
3. A Getinge Sales or Service person will contact the person you listed on the Customer Response Form to schedule service to perform the FSCA of your device, free of charge.

You can find the serial number for your Getinge Drying Cabinet S-363 at the lower part of the front side of the door.



Transmission of this Field Safety Notice:

This Getinge Drying Cabinet S-363 Field Safety Notice needs to be distributed to those individuals who need to be aware within your organization - or to any organization where the potentially affected devices have been transferred.

Please maintain awareness of this notice and resulting action for the use period of the device to ensure effectiveness of the corrective action.

In cases where you as customer choose not to proceed with completion of the corrective action requirements described above, Getinge cannot accept any responsibility for safety related issues or legal liabilities caused by the failure to respond to this Field Safety Notice.

We deeply regret this inconvenience, but we greatly appreciate your understanding as we take actions to ensure correct product performance. If you have any further questions or require assistance completing the Customer Response Form, please contact Getinge.

Sincerely,

Nina Stewén, Local Quality Manager
Getinge Disinfection AB

Signature: *Nina Stewén*

Electronically signed by: Nina Stewén
Reason: I approve this document.
Date: Jun 29, 2026 21:22:55 GMT+2

Email: nina.stewen@getinge.com

Appendix A

Customer Response Form

Field Action 1490032

Reference: Urgent Field Safety Notice, GETINGE Drying Cabinet S-363

Our records indicate that the Getinge Drying Cabinet S-363 device shown below was delivered to your location. Please verify if you have any of the listed devices that are potentially affected and complete the information below.

GETINGE ORDER NO.	ITEM NO.	SERIAL NO.	MANUFACTURING DATE
X	1	XXXX	<Date>
Y	2	YYYY	<Date>

Record the total number of affected device currently located at your facility here please → ____.

Please check the appropriate boxes below:

☐ We have read the Getinge Drying Cabinet S-363 Field Safety Notice and we understand the communication and the required actions.

If checked : please provide information where the affected devices are physically located.

Field Safety Notice Receipt and Customer Response Form Completion and Certification

Current Facility Name			
Contact Name / Title			
Address (no PO boxes)			
City, State, Zip			
Phone Number		Fax:	
E-Mail Address:			

☐ We have sold/moved our Getinge Drying Cabinet S-363 to another facility.

If checked : please provide new facility information below.

New Facility Name			
Contact Name / Title			
Address*			
City, State, Zip			
Phone Number		Fax:	
E-Mail Address:			

PLEASE RETURN YOUR COMPLETED FORM TO:

MAIL

<local SSU address line 1>
 <local SSU address line 2>
 <local SSU address line 3>
 <local SSU address line 4>

CONTACT

<contact address>@getinge.com
 Tel: <SSU contact phone number>
 Fax: <SSU contact fax number>