FIELD CORRECTIVE NOTICE

GETINGE STERICOOL HYDROGEN PEROXIDE PLASMA STERILIZER
Field Action 248440

Date:	4th June 2020
Product Issue:	Wrong Manufacturing Date Problem
Affected Product:	10, Getinge STERICOOL HYDROGEN PEROXIDE PLASMA STERILIZER- All models are affected.
Resolution:	*Getinge propose to replace the all labels of affected devices to make sure all devices present in the market are compliance with regulations.*
Affected Serial Nos.:	A1706321, A1706322, A1706323, A1708394, A1709400, A1709404, A1712413, A1801418, A1802423, A1805446
Field Correction Notice:	The correct labels will be replaced with the old labels which have wrong manufacturing date.
Pages:	3

Dear Customer:

Corrective and preventive action has been initiated to make sure your product is up to the related standards. Getinge technical personnel will come to visit to carry out the action.

Our records indicate that you bought one or more Stericool Sterilizer with model number A110SF, A110DF, A160DF and serial number A1706321, A1706322, A1706323, A1708394, A1709400, A1709404, A1712413, A1801418, A1802423, A1805446.

This letter is to inform you of a corrective action that will be performed on devices listed herein to make sure they have the correct label according to standard.

This action addresses one issues and perform the following corrections:

1. To correct the error in the production date information.

A health hazard analysis was carried out and showed there is no risk to users that needs to be addressed or will be lowered by carrying out this action.

The issue relate mainly to compliancy to standards and not risk to persons/patients. Users/patients are not in any danger. The issue was caused by a typing error. Current production of devices has been checked for the mistake and the issue and the currently sold devices no longer manifest this deficiency.

The action does not affect the device's intend of use or device performance. In additional, the device warrant starts after the device installation. This error has no negative effect on the warranty period of the device.

The devices involved for your facility are limited to those listed herein.

Next Steps

1. Please make sure that all caregivers and users of the Stericool Hydrogen Peroxide Plasma Sterilizer referenced on the previous page are made aware of this Field Notice and all listed devices at your facility are available for the service intervention during the Getinge service technician visit.

2. Complete and sign the enclosed Customer Response Form and return this form to the local Getinge office. **Note**: A Getinge Sales or Service person will contact the person you listed on the Customer Response Form to schedule service to replace your label, free of charge.

Transmission of this Field Notice:

This Getinge Stericool Hydrogen Peroxide Plasma Sterilizer Field 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.

Additional Comment

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

Customer Response Form

Appendix 1 **<Getinge field action number>**

Reference: Urgent Field Safety Notice, Getinge <Device Name>.

Our records indicate that the *<Device Name>* 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 *<Device Name>* 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 *<Device Name>* 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 **CONTACT**

Mubashir.javed@getinge.com