

1.1.1 URGENT - FIELD SAFETY NOTICE

Note This Field action is an update to the previously issued Aperlan Poka-Yoke Agent A & Aperlan Poka-Yoke Agent B

Field Action CAPA 850904

Aperlan Poka-Yoke Agent A & Aperlan Poka-Yoke Agent B Field Action CAPA 850904 UPDATE

Date:	August 04,2023
Product Issue:	Risk of leakage of Aperlan Poka-Yoke Agent A & Aperlan Poka-Yoke Agent B, CAPA 850904
Affected Product:	Aperlan Poka-Yoke Agent A, ref # 41010058 Aperlan Poka-Yoke Agent B, ref # 41010057
UDI DI	No UDI as the product is CE marked according to Directive 93/42/EEC on Medical devices (MDD) and not sold in USA.
SRN	SE-MF-000001012
Resolution:	This FSN contains instruction for customer to discard products of specific lot numbers.
Affected LOT No:	Aperlan Poka-Yoke agent A: 1596531, 1597269, 1597674 Aperlan Poka-Yoke agent B: 1596068, 1597809, 1598089
Field Correction Notice:	N/A
Pages:	7

Dear Customer:

Our records indicate that you have bought one or more canisters of medical device disinfectant Aperlan Poka-Yoke Agent A and Aperlan Poka-Yoke Agent B.

This information is a follow up letter to previously distributed information about the products and will replace, GD12790 Rev A, already communicated. This is to inform you of an action that needs to be performed to prevent issues with these products which could lead to a hazardous situation if not supervised carefully.

The issue:

It has come to our attention that there might be faulty caps/tampering rings on canisters for both disinfectant products Aperlan Poka-Yoke agent A (red cap) and Aperlan Poka-Yoke agent B (blue cap).

This issue could potentially lead to leakage of the product with the risk of causing harm for the operators and staff at hospitals. The products are highly corrosive and also dangerous to the environment.



The disinfection product contained in the canister of Aperlan Poka-Yoke agent A is highly corrosive (pH<1, 20°C) and dangerous for the environment. The alkaline product contained in the canister of Aperlan Poka-Yoke agent B, is also corrosive (pH>13, 20°C).

A leakage of these products could be harmful for users and damaging to material.

It is important to read the Safety Data Sheet (SDS) regarding use of protective equipment during handling of the product. The Safety Data Sheets will be attached to this FSN for your convenience.

[6002473702_MSDS_Aperlan Poka-Yoke Agent A_41010058_XX_RevC](#)

6002473802_MSDS_Aperlan Poka-Yoke Agent B_41010057_XX_RevC

Please follow local requirements and SDS in case of leakage.

The root cause of this issue has not yet been fully identified but specific lot numbers affected by this issue have been isolated and we would like to inform you about certain measures that must be taken to ensure a safe product. LOT numbers can be identified in the location marked above in the photos.

If further actions are required at a later stage, you will be notified.

Action:

Discard any of the affected LOT numbers of Aperlan Poka-Yoke agent A and Aperlan Poka-Yoke agent B within your facility.

Please proceed with the below instructions:

Next steps:

1. Read the Safety Data Sheet (SDS) for Aperlan Poka-Yoke agent A & Aperlan Poka-Yoke agent B and follow the instruction regarding handling and protective equipment.

6002473702_MSDS_Aperlan Poka-Yoke Agent A_41010058_XX_RevC

6002473802_MSDS_Aperlan Poka-Yoke Agent B_41010057_XX_RevC

2. Check the LOT-number on the canister.
3. If any of the canisters at your facility correspond with the LOT number on the Customer response form (Appendix 1), please discard the canister according to your local regulations in terms of dangerous goods.

Do not use any canisters from the affected lot numbers. The efficacy of the product and the safety of the operator cannot be guaranteed.

4. In case of affected canisters, use Appendix 2 for credit note information.
5. Please make sure that all caregivers and users of these products are made aware of this Field Safety Notice.

6. Complete and sign the enclosed Customer Response Form (Appendix 1) and return this form to the local Getinge office.

Transmission of this Field Notice:

This Getinge 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 products have been transferred.

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

In cases where you as customer choose not to proceed with completion of the 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 performance. If you have any further questions or require assistance completing the Customer Response Form, please contact Getinge.

Customer Response Form

Appendix 1

CAPA 850904

Reference: Urgent Field Safety Notice, Aperlan Poka-Yoke Agent A & Agent B

Our records indicate that disinfectant Aperlan Poka-Yoke Agent A & Aperlan Poka-Yoke Agent B with reference number 41010058 (Aperlan A) and 41010057 (Aperlan B) was delivered to your location.

Please verify if you have any of the products listed and complete the information below.

GETINGE PRODUCT NAME	Reference Number	LOT #
Aperlan Poke-Yoke Agent A, 2x5L	41010058	1596531
		1597269
		1597674
Aperlan Poka-Yoke Agent B, 2x5L	41010057	1596068
		1597809
		1598089

Please check the box below and complete with information needed:

- We have read the Urgent Field Safety Notice, Aperlan Poka-Yoke Agent A & Agent B.
By signing this box, we confirm that the information in this letter is understood and that the actions described herein will be followed.

Field Safety Notice Receipt and Customer Response Form Completion and Certification

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

PLEASE RETURN YOUR COMPLETED FORM TO:

lccomplaints,uki@getinge.co.uk

APPENDIX 2

CAPA 850904 Risk of leakage of Aperlan Poke-Yoke agent A & agent B

Please use the table below to record the quantities of discarded canisters. Extend table as needed.

Any credit claims regarding *CAPA 850904 Risk of leakage of Aperlan Poka-Yoke agent A & agent B* will be based on the information provided in this appendix. When the table is completed, sign and send to your local Getinge office.

Discard all canisters from affected lot numbers according to your local regulations in terms of dangerous goods. Please make sure to follow the instructions in the Safety Data Sheet of these products for safe handling and protective equipment.

Name of site: _____

Aperlan Poka-Yoke Agent A		
Ref # 41010058		
LOT number	Qty of canisters	Order number

Aperlan Poka-Yoke Agent B		
Ref # 41010057		
LOT number	Qty of canisters	Order number

<i>Signature & title</i>	<i>Date</i>

Revision History

Rev.	Effective date (DD-MMM-YYYY)	Change Description
A	17-Jul-2023	First release
B	31-Jul-2023	Resolution and affected lot numbers (six specific lot numbers) updated on page 1. Step 2 and forward under “next step”, page 3, changed with new actions. Information to discard all canisters from affected lot numbers according to local regulations in terms of dangerous goods. Information that GD12790 Rev B will replace information communicated in GD12790 Rev A. Appendix 1 updated with the specific lot numbers.