

## FIELD SAFETY NOTICE

<b>Commercial Name of Affected Product</b>	Gen-X Non-Sterile Powder Free Nitrile Examination Glove
<b>FSCA Identifier</b>	Lot number PT751R20S004 and PT764R20S004
<b>Type of Actions</b>	Product replacement

**Date:** 9<sup>th</sup> May 2023

**Attention To:** Customer of Smart Glove International Pte. Ltd.

**Details on affected devices:**

Product name: Gen-X Non-Sterile Powder Free Nitrile Examination Glove

Size: XL

Lot number: PT751R20S004 and PT764R20S004

Manufacturing date: December 2020

Manufacturer: PT Smart Glove, Indonesia.

**Description of the problem:**

The device is found to contain pinholes and tears.

**Advise on action to be taken:**

Review inventory of the affected lot of the product to determine replacement needed and to provide information to representative of Smart Glove International Pte. Ltd. for replacement and purposes of reporting to the authorities.

If you need any further information or support concerning this issue, please contact the below representative.

**Transmission of this Field Safety Notice:**

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

(As appropriate) Please transfer this notice to other organisations on which this action has an impact.

(As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local authorized representative.

**Contact reference person:**

Name: Raihan Bt. Jaafar

Email: [raihan@smartgloveintl.com](mailto:raihan@smartgloveintl.com)

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency.

For and on behalf of

**Smart Glove International Pte. Ltd.**



Chief Commercial Officer

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[info@smartgloveintl.com](mailto:info@smartgloveintl.com)

## Field Safety Notice Acknowledgement /Reply Form

Mandatory fields are marked with \*

1. Field Safety Notice (FSN) information	
FSN Reference number	4 <sup>th</sup> May 2023 (PT751R20S004)
FSN Date	4 <sup>th</sup> May 2023
Product/ Device name	Gen-X Non-Sterile Powder Free Nitrile Examination Glove
Batch/Serial Number (s)	PT751R20S004

2. Distributor/Importer Details	
Company Name*	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Return acknowledgement to Sender	
Company Name	Smart Glove International Pte. Ltd.
Name	Raihan Bt. Jaafar
Email	raihan@smartgloveintl.com
Postal Address	3 Coleman Street #03-24 Singapore 179804.
Web Portal	www.smartgloveintl.com
Deadline for returning the Distributor/Importer reply form	31 <sup>st</sup> May 2023

4. Distributors/Importers (Tick all that apply) *		
<input type="checkbox"/>	I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
<input type="checkbox"/>	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
<input type="checkbox"/>	I have identified customers that received or may have received this device	
<input type="checkbox"/>	I have attached customer list	
<input type="checkbox"/>	I have informed the identified customers of this FSN	Date of communication:
<input type="checkbox"/>	I have received confirmation of reply from all identified customers	
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
<input type="checkbox"/>	Neither I nor any of my customers has any affected devices in inventory	
Name*		
Signature*		
Date *		

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.