

## 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

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

For and on behalf of

**Smart Glove International Pte. Ltd.**



**Ahmad Faizi Mohd Kamil**

Chief Commercial Officer

