FIELD SAFETY CORRECTIVE ACTION NOTICE (REMOVAL)

SPECIFIC PRODUCT LOTS OF:

a) MEDIK PRIME NATURAL LATEX EXAMINATION GLOVES

EVENT REF. NO.: 41189AAA2E1CB

b) MEDIK SECURE VINYL EXAMINATION GLOVES POWDER FREE

EVENT REF. NO.: DFE0443B54292

Date: April 21, 2021

Attention: Saudi Food and Drug Authority and Materials Management Officer of all facilities of users of MEDIK PRIME Natural Latex Gloves in the Kingdom of Saudi Arabia

Dear Valued Customer,

The purpose of this letter is to advise you that Salalah Medical Supplies Mfg. Co. LLC is voluntarily recalling specific affected production lots of MEDIK PRIME Natural Latex Examination Gloves and MEDIK SECURE Vinyl Examination Gloves that were distributed in November of 2018, February of 2020, June of 2020 and July of 2020 in the Kingdom of Saudi Arabia.

Issue Description:

This recall is being conducted due to the specification of the product was assessed by SFDA and found not complying with standards ISO 11193-1:2008/Amd 1:2012 (Single Use Medical Examination Gloves – Part 1: Specification for gloves made from rubber latex or rubber solution) and ISO 11193-2:2006 (Single-use medical examination gloves — Part 2: Specification for gloves made from poly (vinyl chloride) for water tightness and physical properties. While Salalah Medical Supplies Mfg. Co. LLC uses ASTM D3578-19 (Standard Specification for Rubber Examination Gloves) and ASTM D5250-19 (Standard Specification for Poly (vinyl chloride) Gloves for Medical Application) the most common glove standard used in the medical glove industry which has some difference compared to ISO 11193 series and which was not used in the production of the gloves supplied to the Kingdom of Saudi Arabia so we are voluntary recalling the affected lots to preempt potential risk of infection or cross-patient (clinician) exposure to body fluids. To date Salalah Medical Supplies Mfg. Co. LLC is not aware of any reports of patient harm.

Salalah Medical Supplies Mfg. Co. LLC is initiating this voluntary recall on the following lot numbers supplied to customers/users in the Kingdom of Saudi Arabia:

Item Description	Item Code	Lot Numbers
MEDIK PRIME Natural Latex Examination Gloves, Size: Small	167770	19104101
MEDIK PRIME Natural Latex Examination Gloves, Size: Medium	167787	20010502
MEDIK PRIME Natural Latex Examination Gloves, Size: Large	167794	20051903
MEDIK SECURE Vinyl Examination Gloves Powder Free, Size: Small	168210	20062561

MEDIK SECURE Vinyl Examination Gloves Powder Free, Size: Medium	168227	20062562
MEDIK SECURE Vinyl Examination Gloves Powder Free, Size: Large	168234	18010163

This Field Safety Corrective Action affects only the specific lots listed above. SFDA and customers/users in the Kingdom of Saudi Arabia are being notified that Salalah Medical Supplies Mfg. Co. LLC is voluntarily taking this action. We request that you contact Salalah Medical Supplies Mfg. Co. LLC or Omuk Altadamen Medical Est., Authorized Representative if you have experienced quality problems or adverse events with these concerned lots.

Required Actions:

1. CHECK all storage and usage locations to confirm whether you have any units of the affected product lot numbers.
2. Review, complete, sign and return the enclosed Acknowledgement Form in accordance with the directions on the form.
3. Return all affected product or contact your local authorized representative to facilitate return of the affected product. Your sales representative will inform you of the product replacement.
4. Share this letter with others in your facility who need to be made aware of this recall. Contact any other facilities that have been provided with units of affected lot.
5. Maintain awareness of this notice until all affected product has been returned to Salalah Medical Supplies Mfg. Co. LLC.
6. Keep a copy of this notice with any affected product until returned.

We apologize for this inconvenience. If you have any questions or concerns, please do not hesitate to contact your local authorized representative.

Contact Information: Manufacturer

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Managing Director
Salalah Medical Supplies Mfg. Co. LLC
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Contact Information: Authorized Representative

Mr. Salah M. Banakhar
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Mr. Anuruddha Chandrasenna
Quality Control Head

Mr. Salah M. Banakhar
General Manager

Eng. Ahmed Aqil Al-Ibrahim
Managing Director

Salalah Sultanate of Oman P.O.Box : 33/211 C.R.No.2077930 SALALAH MEDICAL SUPPLIES MFG L.L.C

مؤسسة عمق التضامن الطبية س.ت/١٠١٠٥٣٠١٥٤

شركة صلاله لصناعة
المستلزمات الطبية ش.م.م
SALALAH MEDICAL SUPPLIES
MANUFACTURING CO. LLC

FIELD SAFETY CORRECTIVE ACTION CUSTOMER NOTICE REPLY FORM

FIELD SAFETY CORRECTIVE ACTION INFORMATION:

a) FSCA Ref. No. :
b) FSCA Date :
c) Product/Device Name :
d) Product Codes :

e) Product Lot No. :

CUSTOMER DETAILS:

a) Healthcare/Organization Details :
b) Address :
c) Contact Name :
d) Title or Function :
e) Telephone No. :
f) E-mail :

CUSTOMER ACTION UNDERTAKEN: (Please Tick applicable box)

a) I confirm receipt of the Field Safety Corrective Action Notice and I read and understood its content. ☐

b) I performed all actions requested on the Field Safety Corrective Action Notice. ☐

c) The information and required actions have been brought to the attention of all relevant users and executed. ☐

d) I have returned affected devices - enter number of devices returned and date complete. ☐
Qty:
Lot No.:
Date Returned:

e) No affected devices are available for return ☐

f) Other Action (Define): ☐

g) I do not have any affected devices. ☐

h) I have a query please contact me (e.g. need for replacement of the product). ☐

Healthcare Facility/Organization: _____

Responsible Person: _____

Designation: _____

Date: _____

Signature:

Stamp: