MEDITECH GLOVES SDN BHD (580515-T)

PT 3345, JALAN PERMATA 1/3,
ARAB MALAYSIAN INDUSTRIAL PARK,
71800 NILAI,
NEGERI SEMBILAN DARUL KHUSUS,
MALAYSIA
TEL: +6 06 799 7742
+6 06 799 7746
FAX: +6 06 799 7749
http://www.meditechgloves.com

URGENT – Field Safety Notice

To all users of the ExtraFit Latex Examination Gloves, Powdered

Re: ExtraFit Latex Examination Gloves, Powdered with Powder Issue

Dear customer,

This letter is to inform you about a safety concern related to the above-mentioned product which is manufactured by Meditech Gloves Sdn. Bhd. Ensuring patient safety is our top priority, and we have identified a potential issue with this medical device that requires immediate attention.

Product Details -

- Product Name: ExtraFit Latex Examination Gloves, Powdered
- Lot/Batch Numbers: Please refer to Attachment 1
- Manufacturing Dates Affected: Please refer to Attachment 1

Reason for this Field Safety Notice & the potential risks:

Meditech Gloves Sdn. Bhd has initiated a field corrective action for the ExtraFit Latex Examination Gloves, Powdered product due to customer complaints received, indicating issues with uneven powder and clumps that have transferred to both equipment and patients who have come into contact with the gloves despite having powder content well within the specification limit. The products were passed while meeting the specifications at the point of release.

There is no risk to patients/ users and the product can continue to be used, however, to sensitive individuals, this will be a possible cause of allergies, including irritation and/or allergic reactions.

Steps can the user take to avoid the potential risk of this issue:

Discontinue use if there is a sign of irritation or allergic reaction. Users may change to a powder-free type of gloves.

MEDITECH GLOVES SDN BHD (580515-T)

PT 3345, JALAN PERMATA 1/3,
ARAB MALAYSIAN INDUSTRIAL PARK,
71800 NILAI,
NEGERI SEMBILAN DARUL KHUSUS,
MALAYSIA
TEL: +6 06 799 7742
+6 06 799 7746
FAX: +6 06 799 7749
http://www.meditechgloves.com

The issue will be resolved:

Meditech Gloves Sdn. Bhd. is preparing a modification of ExtraFit Latex Examination Gloves, Powdered that will resolve this issue. The field modification will be available from 25th August 2023.

We appreciate your understanding and cooperation with this Field Safety Notice and ask you to immediately instruct your personnel accordingly. Please ensure that this safety notice is placed in the System's instructions for use. Your personnel should maintain awareness over an appropriate defined period.

If you have sold this medical device and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this medical device. Please inform us about the new owner of the medical device.

The **Medical Device Authority** will be informed of this notice.

Sincerely Yours,

Name: Hasnah Abdul Hamid
Designation: Sr. Manager, QA/RA
Date: 19/10/2023

Contact person of this notification	Siti Zulaikha Mohamed Daud
Department	QA/RA
Telephone	012-6504770
Email	zulaikha@meditechgloves.com

MEDITECH GLOVES SDN BHD (580515-T)

PT 3345, JALAN PERMATA 1/3,
ARAB MALAYSIAN INDUSTRIAL PARK,
71800 NILAI,
NEGERI SEMBILAN DARUL KHUSUS,
MALAYSIA
TEL: +6 06 799 7742
+6 06 799 7746
FAX: +6 06 799 7749
http://www.meditechgloves.com

Attachment 1: Lot Numbers Potentially to Have Powder Issue

Mfg. Year 2022

Size	Lot No	MFG Date	Expiry Date
S	222410105	2022-10	2027-09
S	222420105	2022-10	2027-09
S	222430105	2022-10	2027-09
S	222450105	2022-11	2027-10
S	222470105	2022-11	2027-10
S	222480105	2022-12	2027-11
S	222490105	2022-12	2027-11
S	222500105	2022-12	2027-11
M	322360105	2022-09	2027-08
M	322410105	2022-10	2027-09
M	322420105	2022-10	2027-09
M	322430105	2022-10	2027-09
M	322440105	2022-11	2027-10
M	322450105	2022-11	2027-10
M	322470105	2022-11	2027-10
M	322480105	2022-12	2027-11
M	322490105	2022-12	2027-11
M	322500105	2022-12	2027-11
M	322510105	2022-12	2027-11
L	422410105	2022-10	2027-09

Mfg. Year 2023

Size	Lot No	MFG Date	Expiry Date
S	223010105	2023-01	2027-12
S	223020105	2023-01	2027-12
S	223060105	2023-02	2028-01
S	223090105	2023-03	2028-02
S	223120105	2023-03	2028-02
M	323010105	2023-01	2027-12
M	323020105	2023-01	2027-12
M	323060105	2023-02	2028-01
M	323070105	2023-02	2028-01

MEDITECH GLOVES SDN BHD (580515-T)

PT 3345, JALAN PERMATA 1/3,
ARAB MALAYSIAN INDUSTRIAL PARK,
71800 NILAI,
NEGERI SEMBILAN DARUL KHUSUS,
MALAYSIA
TEL: +6 06 799 7742
+6 06 799 7746
FAX: +6 06 799 7749
http://www.meditechgloves.com

Size	Lot No	MFG Date	Expiry Date
M	323080105	2023-02	2028-01
M	323090105	2023-03	2028-02
M	323100105	2023-03	2028-02
M	323110105	2023-03	2028-02
M	323120105	2023-03	2028-02
M	323130105	2023-03	2028-02
L	423070105	2023-02	2028-01
L	423100105	2023-03	2028-02
L	423130105	2023-03	2028-02
L	423140105	2023-04	2028-03