Mymedic Innovation Sdn Bhd
200601037776 (757536-K)
No. 8, Lorong Sukepi 1, Off Jalan Sukepi, Kawasan Perindustrian Jenjarom,
42600 Jenjarom, Selangor Darul Ehsan.
+60 3 3191 4868 +60 3 3181 7868
enquiry@mymedic.com.my SST B10-1812-22100009

(June, 26, 2024)

URGENT: MEDICAL DEVICE RECALL ULTRASOUND GEL 5 KG (USG90402)

Pharmaniaga Logistics Sdn Bhd,
7 Lorong keluli 1B,
Kaw. Perindustrian Bukit Raja Selatan,
Seksyen 7, 40000 Shah Alam, Selangor.
No. tel: 03-33429999
(**u.p: Customer Care and Recall Unit**)

Dear Device Customer,

Purpose of this letter

The purpose of this letter is to advise you that Mymedic Innovation Sdn Bhd is mandatory recalling Ultrasound Gel 5kg with lot details (**USG402-2306**). The intended of product is used to improve the transmission of sound waves during ultrasound procedures and for external use only.

The class of recall for this mandatory recalling is **Class II – Medium risk**. Represents a medium risk, which is less risk than the Class I recall. In a Class II recall, there is either a probability that the device will cause temporary or reversible health consequences, or there is remote probability that the device will cause serious consequences.

This letter is to formally notify recipients of a recall concerning an Ultrasound gel product by Mymedic was found to be contaminated with Burkholderia cepacia complex (BCC) bacteria. This recall notification aims to inform recipients about the affected product, Ultrasound Gel 5kg, with batch USG402-2306. Burkholderia cepacia complex (BCC) bacteria, which contaminated the gel, can pose serious health risks, particularly to individuals with weakened immune systems or chronic lung diseases, such as cystic fibrosis. The health risks associated with the contaminated gel include respiratory infections, bloodstream infections, skin and soft tissue infections and antibiotic resistance.

The letter provides clear instructions on the necessary steps to take, such as discontinuing use immediately and returning the product for the replacement. Additionally, the letter offers support by providing customer service contacts and support helplines for further assistance. This communication demonstrates the company's commitment to transparency, customer safety, and quality assurance by addressing the contamination issue promptly and effectively to protect customers.

Reason for the Mandatory recall:

The Ultrasound Gel 5kg with product code USG90402 from lot number USG402-2306, expired on May 2026 manufactured by Mymedic Innovation Sdn Bhd has been found to be contaminated with Burkholderia cepacia complex (BCC) bacteria.

- **Contamination / Decontamination problem (**Problem associated with the presence of any unexpected foreign substance found in the Ultrasound Gel, on its surface or in the package materials, which may affect performance or intended use of the Ultrasound Gel, or problem that compromise effective decontamination of the Ultrasound Gel.)

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- **Use of Device Problem** (Problem associated with failure to process, service, or operate the device according to the manufacturer's recommendations or recognized best practices.)

Risk to health:

The contaminated gel can cause serious infections, especially when applied to mucous membranes, broken skin, or wounds. This poses a high risk for users with compromised immune systems or chronic conditions.

Use on broken skin or wounds can introduce BCC bacteria into the bloodstream, potentially causing bacteremia or sepsis. This condition is life-threatening and characterized by fever, chills, rapid heartbeat, and confusion.

Actions to be taken by the customer/user:

the necessary steps to take, such as;

- discontinuing use the affected medical devices (**USG402-2306**) immediately,
- removal of the affected medical devices (**USG402-2306**) from its current operation location,
- quarantine the affected medical devices (**USG402-2306**),
- return the affected medical devices (**USG402-2306**) to the establishment of the medical device.

Product and distribution information:

Product and Distribution Information Table					
Product name	Manufacturer's Product number	Lot/ Serial number	Manufacturing/ Distribution dates	Expiry date	Quantity (pack of 5kg)
ULTRASOUND GEL 5KG	USG90402	2306	JUN 2023	MAY 2026	912

Type of action by the company (if applicable):

Improve Field Safety Notice (FSN) Content, provide QR code of FSN at each product label 5kg, Refillable bottle and 260g individual bottle, and improve labeling by add critical information.

- **Investigation findings:** All requirement action has been taken just to ensure that our Ultrasound gel is safe to use by our customer. Our Ultrasound gel will undergone the microbiological test before it permitted to be release in market. However, as on finding we found the possible root cause of the incident due to handling of the product during storage after use at user side.

  Next, User not aware of the type of gel is non-sterile product. And, different method of testing to detect the present to BCC. Even FSN already inside the carton box, user still did not aware because the FSN did not reach to them

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Other information:

a) Contact information for questions.

- Email: customercare@mymedic.com.my
- Contact. No: 03-3191 4868

b) Attachments of Acknowledgment and Receipt Form (separate sheets).

Authorized by:

Name: Mohamad Farkhan Bin Damri

Signature:

Title: Director of Mymedic Innovation Sdn Bhd

MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgment and Receipt Form

Response is required*

Customer Information:
Customer Name:
Address:

ULTRASOUND GEL 5KG

Please distribute this information to the appropriate personnel at your facility including surgeons who may have received the product which is the subject of this recall notice.

Lot/Serial numbers: USG402-2306

I have read and understand the recall instructions provided in the 26 June 2024 letter.

Yes _ No _

Any adverse incidents associated with recalled product?

Yes _ No _ If yes, please explain:

_____

_____

Was this device implanted? (If yes, please specify the implant dates, the quantities implanted, and provide available tracking information).

Affected product information: Include information that is applicable for affected product.

Affected Product Information Table			
Product/ Brand names, UDI (if applicable)	Manufacturer's Product number/ Catalogue number	Lot/ Serial number shipped to customer	Quantity in inventory/ returned
ULTRASOUND GEL 5KG	USG90402	2306	

Return Response Box:

Please provide any additional information, if applicable.

PLEASE RETURN COMPLETED RESPONSE FORM TO: Fax. 03-3181 7868,

ATTN: Customer Care Unit
OR MAIL TO: customercare@mymedic.com.my