



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

(Aug, 05, 2024)

URGENT: MEDICAL DEVICE RECALL BLOOD GIVING SET COMPLETE (BGS80623 / 17.0601.01)

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 Voluntary recalling Blood Giving Set Complete with lot details (BGS623-2308). The intended of product is used in intravenous blood transfusion while preventing exposure to intragenic cross-infection. Mainly use for intravenous blood transfusion.

The class of recall for this Voluntary recalling is **Class III – Low risk**. Represents the lowest risk. In a Class III recall, there is low probability that using or being exposed to a device will cause health consequences. By considering that the product is having problem, there is still a need to take an action to address the problem.

This letter is to formally notify recipients of a recall concerning a Blood Giving Set Complete device by Mymedic was found to be leaking on Y-site injection port. This recall notification aims to inform recipients about the affected product, Blood Giving Set Complete, with batch BGS623-2308. The leaking caused may contributed to insufficient delivery of medication of treatment to a patient in which the potential actual amount delivered to the patient may be less then prescribed.

The letter provides clear instructions on the necessary steps to take, such as discontinuing use immediately and returning the product for the product exchange. 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 these issue promptly and effectively to protect customers.

Reason for the Voluntary recall:

The Blood Giving Set Complete with product code BGS80623 (17.0601.01) from lot number BGS623-2308 expired on July 2028 manufactured by Mymedic Innovation Sdn Bhd has been found leaking on Y-site injection port which tend to insufficient delivery of medication treatment.

- **Infusion or Flow Problem;** Problem associated the Blood Giving Set complete may failing to deliver liquids as the intended used in intravenous blood transfusion while preventing exposure to intragenic cross-infection. Mainly use for intravenous blood transfusion.



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Risk to health:

The leaking issue during a blood transfusion poses to reduced dosage, If a device intended to administer leaks, the actual amount delivered to the patient may be less than prescribed.

Actions to be taken by the customer/user:

the necessary steps to take, such as;

- discontinuing use the affected medical devices (**BGS623-2308**) immediately,
- removal of the affected medical devices (**BGS623-2308**) from its current operation location,
- quarantine the affected medical devices (**BGS623-2308**),
- return the affected medical devices (**BGS623-2308**) 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 (set)
BLOOD GIVING SET	BGS80623	2308	AUG 2023	JUL 2028	195,000

Type of action by the company (if applicable):

Improve on current checking at rubber side of injection port had been implemented. Currently checking method after found leaking has been emphasized to minimal such of issue from occurrence. The cut off improvement device is on batch no. BGS623-2309

- **Investigation findings:** We suspect for this occurrence is due to rubber mould faulty during the startup process. This caused the shape of rubber slightly changed during the startup production. Due on that, this has caused a minor gap between the rubber and the plastic this, unconditionally caused the occurrence of leaking.

However, as to avoid this issue from arising, we decide to recall the device from batch no. BGS623-2308 which still left at market. This countermeasure taken is to ensure that any potential issues related to the Y-site injection ports in batch no. BGS623-2308 are addressed promptly.



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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:

BLOOD GIVING SET COMPLETE

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: BGS623-2308

I have read and understand the recall instructions provided in the 05 Aug 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
BLOOD GIVING SET	BGS80623	2308	

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