



Urgent Field Safety Notice

Device affected: **Gamete Buffer – Lot number B0812**

FSCA-number: **CAPA 2023-01**

Type of action: **Recall - Destroy all stock of B0812**

ID: This is an initial Field Safety Notice

Date: 12th January 2023

Attention: Customers from Kitazato who have used this Gamete Buffer lot.

Contact details: end-users of Kitazato or competent authorities of countries where Kitazato marketed the product, must contact Kitazato.

Device affected:

Product name: Gamete Buffer
Lot number: B0812
Production date: 27th of August 2021
Expiry date: 31st of August 2022
(Basic UDI Kitazato¹: **458223146GBDGL**):

Product code Kitazato	Number	UDI
GBD- 100	100	Bottle: (01) 04582231467273 (17) 230228 (10) B0812 Box: (01) 14582231467270 (17) 230228 (10) B0812

Device type: CE marked medical device

Intended use: Gamete Buffer is used for washing and handling of human gametes and embryos outside the incubator, during ICSI (Fertilization by intracytoplasmic sperm injection), IUI (Intra-uterine insemination) washing or swim-up of human spermatozoa and embryo transfer procedures

¹ Note that this batch was CE marked in accordance with the Medical Device Directive 93/42/EEC. Basic UDI is assigned as from Kitazato in accordance with the Medical Device Regulation 2017/745.

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Background:

The composition of Gamete Buffer media is based on Earle's balanced salts solution. The medium is made to a physiological pH and salt concentration. Balanced salt solutions are used for washing tissues and cells and are usually combined with other agents to treat the tissues and cells. They provide the cells with water and inorganic ions, while maintaining a physiological pH and osmotic pressure. Gamete Buffer Media are sold worldwide to support the techniques used for assisted reproduction.

Gamete Buffer GBD-100 shelf-life is defined as 12 months from date of manufacture.

Description of the problem:

Kitazato recently received information about incorrect expiry date on the product label.

Although lot B0812 was released according to the specifications, it cannot be ensured that this product still performs well. Therefore, Kitazato decided to start a Field Safety Corrective Action (FSCA) to destroy all stock of B0812 ensuring high levels of quality their products have always proudly demonstrated.

Action to be taken:

- Please destroy all remaining stock of Gamete Buffer - lot B0812 at your site. Please take a photo of the products that will be destroyed. **Do this within 24 hours.**
- Please **immediately** inform all of your customers to whom you have distributed affected product. If English is not an official language in your country, please translate this letter and provide the translation to the end-users. Request that they destroy all remaining stock of Gamete Buffer - lot B0812 and request a confirmation of **this within 24 hours.**
- Complete accompanying form and return it **within 24 hours** to Kitazato (regulatory@dibimed.com).

We will replace or credit back the remained stock .

In order to perform a thorough investigation of this issue, if you already have used Gamete Buffer - lot B0812 in your procedures after August 31st, 2022, it would be helpful to receive your feedback and results.



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Kitazato will investigate this incident in-depth and will take appropriate corrective and preventive actions (CAPA), as applicable.

- Internal investigation is on-going to determine the cause of the incorrect labelling.
- Implementation of actions to avoid mislabeling are being implemented.

Any questions regarding this Field Safety Notice may be forwarded to regulatory@dibimed.com. Kitazato remains strongly committed in providing the best possible quality products. We apologize for the inconvenience this situation may have caused.

Thank you for your cooperation,

Kind Regards,

Kyoko Izumi
Regulatory Affairs Manager

Kitazato Corporation

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E-mail: ce_registration@kitazato.co.jp



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Attached to this Urgent Field Safety Notice:

- Attachment 1: FSCA_Device recall response form for customers