

URGENT FIELD SAFETY NOTICE – PRODUCT RECALL

Product name: *KliniTray*

FSCA Identifier: Precautionary recall due to potential sterility issue

Type of action: Field Safety Corrective Action (FSCA) – Product Recall / Use Restriction

Date: 03.04.2025

Attention!

Please read this safety notice carefully and take the actions described below **immediately**.

Details of affected product

- **Product name:** KliniTray
- **Risk class:** MDR Class Is
- **Sterile packaging:** X-ray sterilisation
- **Affected LOT numbers:** 25.018.01; 25.018.02; 25.019.01; 25-020.01; 25.021.01; 25.021.02; 25.022.01; 25.023.01
- **Order/reference number(s):** 2001105; 2001155; 2001205; 2001255

A complete list of affected products can be found in **Annex 1** of this notice.

Description of the issue

As part of our internal quality assurance program, a routine “Dose Audit” was conducted on one specific batch of the product KliniTray. During this audit, **2 out of 10 tested units** showed **positive microbial growth**. The affected batch has been **quarantined immediately** and was **not released to the market**.

However, since other batches were also produced in the **same production period**, a **potential risk to sterility** cannot be completely ruled out. Therefore, this **precautionary recall** is being carried out.

If affected products were used assuming they are sterile, there is a potential **risk of infection**, particularly in sterile environments like the operating room. At this time, **no harm or patient incidents** have been reported.

Actions to be taken by the distributor

Please take the following actions **immediately**:

- **Identify and quarantine all units** of the affected LOT numbers (see Annex 1).
- **Do not distribute or use these products.**
- **Treat the products as non-sterile (clean packed)** and ensure they are **not used on the sterile field**.
- **Inform all relevant departments or customers** within your distribution chain about this FSCA.
- **Complete and return the acknowledgment form (Annex 2)** by **16.04.2025**, even if you no longer have affected stock.

Transmission of this Field Safety Notice (if applicable)

Please ensure that this notice is shared with all persons in your organization who need to be informed.

If you have forwarded the affected products to any third parties (e.g., hospitals, resellers), **please forward this notice accordingly.**

Keep a record of this notice and all related actions for an appropriate period to ensure the effectiveness of the corrective action.

Contact for questions or returns

Contact person:

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Annexes

- **Annex 1:** List of affected LOT numbers
- **Annex 2:** Acknowledgment / Response form

We apologize for the inconvenience this may cause and thank you for your immediate cooperation in this matter. Patient safety remains our highest priority.

Sincerely,
Sylvia Kitta

PRRC

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