
Urgent Safety Information

Recall concerning

Inflation-/deflation system GDB-10-30-030

Achenmühle, xx. April 2016

Vendor:

Medi-Globe GmbH
Medi-Globe-Strasse 1 – 5
83101 Achenmühle
Germany

Addressee:

User of below mentioned medical products (Inflation-/deflation system)

Klinik, Praxis
Adresse
Ggf Postfach

PLZ Ort

Dear Sir or Madam,

Kindly note that we need to recall our product GDB-10-30-030:

Identification of relevant items:

LOT: 15095001
15095361
15105451
15115264

Quantity:

Description of problem:

Our supplier informed us about possible damage of the primary packaging (blister), which can affect product sterility.

We were informed that the primary packaging (blister) within the above-mentioned lot-number(s) shows in some cases a clear crack, visible and always located at the same place (near the handle or the pressure gauge).

The internal investigation of our supplier confirms that this error rarely occurs.

Risk to patient:

The defect can be easily identified by the user in the required visual inspection for the integrity of the packaging, which is requested by the user instructions.

Otherwise, there is a patient's risk of microbial contamination (infection) caused by the use of a product where the sterility is not guaranteed due to a damaged primary packaging (blister).

To date, no adverse effect has been reported on the health and safety of the patients that may be associated with this problem.

What measures need to be achieved by addressee?

Based on the traceability, we have determined that you received potentially affected products.

For this reason we would like to ask you for the following assistance:

1. Please check if you still have products from the above-mentioned lot-number(s).
2. Please check the potentially affected lot-number(s) for visible cracks of the primary packaging (blister).
3. The undamaged products can be used without risk.
The damage to the primary packaging (blister) does not occur at a later date. If there is no crack in the primary packaging (blister), the integrity of the product is unaffected.
4. Do not use the damaged products.
5. We kindly ask you to inform us as soon as possible how many products of the affected lot-number(s) have not been used and are damaged. Please send back these goods along with the filled in document.

Please send us all unused products with a damaged primary packaging (blister) of these lot-number(s) back to the following **return address**:

Medi-Globe GmbH
Südring 21
46342 Velen-Ramsdorf

Please make sure that all relevant persons get to know of this urgent security information.

In case you've handed over above items to a third party please make sure to forward them this information and inform below mentioned contact person.

The authorities for drugs and medical items received a copy of this urgent security information.

Contact person at Medi-Globe GmbH:

Reinhard Goswin
Medi-Globe-Strasse 1 – 5

83101 Achenmühle

Tel.: 08032 / 973 - 155
Fax: 08032 / 973 - 394
E-Mail: Goswin@medi-globe.de

Kind regards

Reinhard Goswin

Customer response form
FAX Number to reply 0049 8032 / 973-394

Recall for Medi-Globe Inflation-/deflation system

Item number	GDB-10-30-030
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LOT:	

Following products are in our storage:
 (Don't use the products, return them to Medi-Globe please!)

Item number	LOT	Quantity
GDB-10-30-030		

No products in our storage.

Vendor:

Person
 responding:

Tel. No.

Remarks:

Please follow the procedure:

- 1. Please fill in this form completely, even if you have no more products in stock.**
- 2. Please send the filled form to Fax No.: +49 (0)8032 / 973-394**

date:

Signature / function

Please fax this form as quickly as possible