

Medi-Globe GmbH, Medi-Globe-Str. 1-5, 83101 Rohrdorf / Achenmühle, Germany

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28.02.2022

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**Field Safety Notice**

Recall concerning

**GUS-42-18-022 EBUS TBNA Ultrasound Needle System**

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Dear Sir or Madam,

With this letter we would like to inform you about a recall of our product GUS-42-18-022 EBUS TBNA Ultrasound Needle System and ask you to take note:

Identification of the medical devices concerned:

<b>Artikel number (REF)</b>	<b>Batch number (LOT)</b>	<b>Quantity</b>
GUS-42-18-022	G2119357	65
GUS-42-18-022	G2100198	15
GUS-42-18-022	G2100198	10
GUS-42-18-022	G2119628	110
GUS-42-18-022	G2122757	100
GUS-42-18-022	G2133718	100
GUS-42-18-022	G2136526	120
GUS-42-18-022	G2131333	30

**Description of the problem:**

We have been informed of a qualitative problem with the above-mentioned product, so that unrestricted, safe treatment of the patient can no longer be guaranteed.

Although the investigation results so far do not show a clear cause, we are conducting a precautionary recall for the potentially affected batches.

**Patient risk & recommendation for further action:**

The safety and performance of the product cannot be fully guaranteed. Based on the current state of knowledge, we advise against its use.

**What measures are to be taken by the addressee?**

Upon tracing, we have determined that you have received affected products. For this reason, we ask you for the following support:

1. please check if you still have products in stock from the above batch numbers (LOT).
2. Set the use of all affected lot numbers (LOT) in your possession.
3. Separate the batch numbers concerned (LOT) to avoid unauthorized access
4. forward this **"Urgent Safety Information"** to all persons in your institution who need to be informed. If you have passed on the product, please identify the facilities/departments concerned and forward this notification to them immediately.

Please keep this information at least until the measure has been completed. The Federal Institute for Drugs and Medical Devices has received a copy of this **"Urgent Safety Information"**.

5. Please complete the attached **reply form** and return it by fax or email **immediately, but no later than 2022-03-31**, to be able to offer you an alternative as quickly as possible or to coordinate the return shipment of the affected items.

If you have any questions, we are always at your disposal.

**Contact person at the company MEDI-GLOBE:**

**Stefanie Schaal**  
Medi-Globe-Straße 1-5  
83101 Rohrdorf

Tel.: +49 8032 973 334  
E-Mail: sales@medi-globe.de

Best regards

Gerald Stegemann  


**Gerald Stegemann, PRRC Medi-Globe GmbH**

## Reply form

Please, respond via e-mail to [sales@medi-globe.de](mailto:sales@medi-globe.de)

**GUS-42-18-022** EBUS TBNA Ultrasound Needle System

We have the following number of affected products in stock:  
 (Please do not continue to use products and return them to MEDI-GLOBE!)

Artikel number (REF)	Batch number (LOT)	Quantity
GUS-42-18-022	G2119357	65
GUS-42-18-022	G2100198	15
GUS-42-18-022	G2100198	10
GUS-42-18-022	G2119628	110
GUS-42-18-022	G2122757	100
GUS-42-18-022	G2133718	100
GUS-42-18-022	G2136526	120
GUS-42-18-022	G2131333	30

We do not have any affected product in our inventory.

Sender:

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Contact person:

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Tel. no.:

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Remark:

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Date:

Signature / Function

Please proceed as follows:

1. Complete the reply form in full, even if you no longer have any products in stock.
2. Please send the completed reply form to the following e-mail address: [sales@medi-globe.de](mailto:sales@medi-globe.de)

Geschäftsführer/Managing Director: Christian Klein, Martin Lehner, Ralph Rothe, Marko Rudnicki

Handelsregister/Registration: HRB 4270 Amtsgericht Traunstein

USt-ID-Nr.: DE131556319

Hypo Vereinsbank, Rosenheim

IBAN: DE05 7112 0077 0025 5885 92

BIC (Swift): HYVEDEMM448

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