

Ludwig Bertram GmbH Postfach 10 01 52 30901 Isernhagen, Germany

Date: 24.01.2024

Urgent safety information
Corrective action RUSSKA
laguna bath seat (article no.: 78700 000) and
laguna bath seat with backrest (article no.: 78700 100)

Sender:

Ludwig Bertram GmbH, Im Torfstich 7, 30916 Isernhagen, Germany

Addressee:

Medical supply retailers who have received the above-mentioned product.

Identification of the medical device concerned:

Medical device	REF	Serial number
laguna bath seat	78700 000	From 00000001 to 00000961
laguna bath seat with backrest	78700 100	From 00000001 to 00000540

Laguna bath seats that we delivered to medical supply retailers in the period from **April 2024 to August 2024**.

Description of the problem including the identified cause:

Laguna bath seats placed on the market in the period from April 2024 to August 2024 have a defective locking mechanism of the side struts due to faulty manufacturing. As a result, there is a risk of the bath seat shifting or moving during use, resulting in an unsafe sitting position. This can increase the risk of a fall. This risk only occurs with laguna bathtub seats from deliveries of the above-mentioned period.

What measures are to be taken by the addressee?

With your help, we would like to avoid potential risks for users:

1. in the attachment to this letter (reply form) you will find a list of deliveries that contained products affected by this measure.
2. check whether you still have laguna bath seats and/or bath seats with backrest with the relevant serial numbers in stock.
3. with immediate effect, do not deliver any laguna bathtub seats and/or bathtub seats with backrest with the affected serial numbers.
4. inform the users known to you by name who have been supplied with laguna bathtub seats and/or bathtub seats with backrest with the serial numbers in question about the existing risk and ask them to stop using the products and dispose of them.
5. please return the attached response form to us by 15th February 2025

6. our internal sales department will then contact you for individual arrangements to replace the affected stock items with new bath seats.

If you have any questions about this urgent safety information, please contact our **internal sales team**:

Contact: Mrs Sabine Freitag
Telephone: +49 5136 9759 0
E-mail: freitag@russka.de

Passing on the information described here:

Please ensure in your organisation that all affected users of the above-mentioned products and other persons to be informed are made aware of this Urgent Safety Information. If you have passed the products on to third parties, please forward a copy of this information or inform the third parties concerned.

Please keep this information at least until the measure has been completed.

The Ministr of Healthg has received a copy of this urgent safety information.

We regret this incident and apologise for any inconvenience caused. Our aim is to prevent possible harm to end users.

Kind regards

Thomas Ritter
Management

Dr. Gesine Köhne
PRRC

Attachments

Response form

Urgent safety information response form - letter dated 24 January 2025

Please return the response form to us by 15 February 2025 (fax: +49 5136 9759-555 or e-mail: freitag@russka.de).



Company: _____ Contact person: _____

Customer number: _____ Place, date: _____

Signature: _____

Medical device	REF	Serial number	Quantity delivered	In voice number	Invoice date	(A) Number in stock	(B) Number of customer who cannot be identified	(C) Number of customers known by name who have been informed of the action
laguna bath seat	78700 000	From 00000001 to 00000961						
laguna bath seat with back rest	78700 100	From 00000001 to 00000540						