



Ludwig Bertram GmbH Lockbox 10 01 52 30901 Isernhagen Germany

July 21st 2023

**Urgent safety information**  
**Corrective action RUSSKA**  
**laguna shower stool (order number: 78700 600) and**  
**laguna shower seat (order number: 78700 400, -500, -700)**

**Sender:**

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

**Addressee:**

Specialist dealers who have received the said products.

**Identification of the affected medical device:**

Medical device	Order number	Serial number
laguna shower seat	78700 400	from 00001935 to 00002874
laguna shower seat with backrest	78700 500	from 00001635 to 00001954
laguna shower stool with armrests	78700 600	from 00014658 to 00024391
laguna shower seat with backrest and armrests	78700 700	from 00008149 to 00015961

laguna shower stools and shower seats supplied by us to specialist dealers in the period  
**January 2022 to March 2023.**

**Description of the problem including the identified cause:**

Herewith we would like to inform about a safety risk for users with a body weight in the limit range of the maximum user weight with some products of the laguna bath series. The products of the laguna bath series are already established on the market since 2017 and comply with all requirements of MDR 2017/745 that are applicable. However, it has become apparent that laguna shower stools and shower seats from delivery January 2022 to March 2023 may break when used by users with a body weight in the limit range of the maximum user weight (from approx. 124 kg to 150 kg) and users may injure themselves as a result. As a safety measure, we have reduced the maximum load capacity of the products with the affected serial numbers to 109 kg.



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

During the relevant period, you have received a total of the following laguna shower stools and/or shower seats with the affected serial numbers:

Medical device	Order number	Serial number	Quantity
laguna shower seat	78700 400	from 00001935 to 00002874	
laguna shower seat with backrest	78700 500	from 00001635 to 00001954	
laguna shower stool with armrests	78700 600	from 00014658 to 00024391	
laguna shower seat with backrest and armrests	78700 700	from 00008149 to 00015961	

With your help, we would like to avoid possible hazards for the users:

1. Check whether you still have laguna shower stools and/or shower seats with the relevant serial numbers in stock.
2. Do not deliver laguna shower stools and/or shower seats with the respective serial numbers from now on.
3. Inform the users known to you by name with a body weight of **110 kg or more** who have been supplied with laguna shower stools or shower seats with the relevant serial numbers about the existing risk and request them to stop using the products and to dispose them.
4. If you do not know the weight of users known by name, please contact the relevant users and ascertain their weight. If you can identify users with a body weight of **110 kg or more**, inform them of the existing risk and ask them to stop using the products and dispose them.
5. Please return the attached response form to us by **15th August 2023** with the following information:
  - **(A)** Number of affected laguna products you currently have in stock (no stock, please enter "0" for number in stock).
  - **(B)** Number of customers **known by name** who have been supplied by you with the affected laguna products, with a body weight **below 110 kg**.
  - **(C)** Number of customers **known by name** who were supplied by you with the affected laguna products, for whom you could **not determine the weight**.
  - **(D)** Number of customers **not known by name** who have been supplied by you with the affected laguna products.
  - **(E)** Number of customers **known by name** who have a body weight of **110 kg or more**. Please note the name, supply date and weight for this group of customers in the table so that we can supply these customers with an adequate product.
  - For all subsequent steps, our internal sales team will contact you for individual arrangements.

If there is not enough space in the table provided, you can request the template as an Excel file from our internal sales department.



**Passing on the information described here:**

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

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

The Federal Institute for Drugs and Medical Devices has received a copy of this Urgent Safety Information.

**Contact person:**

Ludwig Bertram GmbH  
[REDACTED] (PRRC)  
Im Torfstich 7  
30916 Isernhagen  
Germany  
Phone: 05136 9759 [REDACTED]  
E-mail: [REDACTED]

**Internal Sales:**

Ludwig Bertram GmbH  
Im Torfstich 7  
30916 Isernhagen  
Germany  
Phone: 05136 9759 [REDACTED]  
Fax: 05136 9759 [REDACTED]  
E-mail: [REDACTED]

We regret this procedure and apologise for the inconvenience caused to you. Our goal is to prevent possible damage to end consumers.

If you have any questions, please do not hesitate to contact us.

Kind regards,

[REDACTED]  
*Management*

[REDACTED]  
*PRRC*

**Attachments**

Response form



**Urgent Safety Information Response Form - Letter dated July 21st 2023**

Please return the response form to us by 15th August 2023 (fax: [redacted] or e-mail: [redacted]).

Company: \_\_\_\_\_

Contact person: \_\_\_\_\_

Customer no.: \_\_\_\_\_

Place, date: \_\_\_\_\_

Signature: \_\_\_\_\_

Medical device	Order number	Serial number	Quantity supplied	(A) Number in stock	(B) Number of customers known by name - weight below 110 kg	(C) Number of customers known by name - Weight not determinable	(D) Number of customers not known by name	(E) Affected customers with a weight from 110 kg			
								Number of customers affected	Name customer	Supply date	Weight in kg
laguna shower seat	78700 400	from 00001935 to 00002874	,								
laguna shower seat with backrest	78700 500	from 00001635 to 00001954									
laguna shower stool with armrests	78700 600	from 00014658 to 00024391									
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