



Am Ockenheimer Graben 50  
55411 Bingen  
Telefon (06721) 90 6-0  
Telefax (06721) 90 6-66

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# Urgent Safety Information (FSN)

## Recall concerning: Rehabuggy Multiroller

**Date:** 26 February 2026

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### Sender

**RehaNorm GmbH & Co. KG**  
Am Ockenheimer Graben 50  
55411 Bingen-Kempton

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### Recipients

Medical supply stores according to the RehaNorm CRM system

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## 1. Identification of the affected products

- **Product name:** Rehabuggy Multiroller
- **Models:** Jogger / Buggy / Offroad
- **Risk class:** Class I (MDR)
- **Affected batches/serial numbers:** See Annex 1
- **Manufacturing period:** 27 June 2025 - 13 February 2026

The article numbers and serial/batch numbers relevant to your medical supply store were already sent to you by e-mail on 25 February 2026 and 26 February 2026.

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## 2. Description of the problem including the identified root cause

Internal quality monitoring identified a potential **mechanical weakness in the rear frame joints** of certain units.

Possible consequences under load:



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- Breakage of the rear frame joints
  - Uncontrolled movement within the joints
  - Instability of the Multiroller

This constitutes a safety-relevant risk.

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### 3. Risk to patients and users

Breakage of the rear frame joints may result in:

- Fall incidents
- Injuries to patients
- Injuries to users

Risk assessment according to ISO 14971: **Risk level: high.**

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### 4. Description of the Field Safety Corrective Action (FSCA)

RehaNorm GmbH & Co. KG is conducting a **Field Safety Corrective Action (FSCA)** in the form of a **product recall**.

The measure includes:

- Retrieval of all affected Multiroller units
  - Replacement of the affected component after inspection by TÜV Süd
  - Free-of-charge processing for customers and patients
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### 5. Actions to be taken by the recipient

Please carry out the following steps immediately:

- Block all affected stock items
- Retrieve delivered products from customers
- Return the completed response form
- Send returns to:

**RehaNorm GmbH & Co. KG – Recall Department**  
Am Ockenheimer Graben 50  
55411 Bingen-Kempton



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## 6. Forwarding of this information

Ensure that all users of the affected products and all other relevant persons within your organisation receive this Urgent Safety Information.

If you have supplied the products to third parties, forward a copy of this information or notify the contact person listed below.

Please retain this information until the corrective action has been completed.

A copy of this notice has been provided to the **Federal Institute for Drugs and Medical Devices (BfArM)**.

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## 7. Confirmation of implementation

Please return the completed response form without delay.

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## 8. Contact person

**Andrea Staus**

Phone: +49 (0) 6721 9060

E-mail: [info@rehanorm.de](mailto:info@rehanorm.de)

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## Attachments

- Annex 1: List of article numbers with serial/batch numbers
- Annex 2: Response form
- Annex 3: Return label

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## Signature

Andrea Staus (CEO)