

Name
Addition
Street
LOCATION

Urgent safety information

**Corrective action
concerning
KayserBett OLAF paediatric care bed**

08 Oct. 2024

Sender:

KayserBetten GmbH & Co KG, Rieper Str. 12, 29683 Bad Fallingbostel
SRN: DE-MF-000006910

Addressee:

Specialist dealers, operators and users

Identification of the medical devices concerned:

Product category	Product designation	Basis UDI-DI
Paediatric care bed	KayserBett OLAF 98	426038961OLAF98AE
Paediatric care bed	KayserBett OLAF 135	426038961OLAF135D5

For affected serial numbers from year of manufacture 2023, see table in Appendix II

Description of the problem including the identified cause:

The storage location of the handcontrol is within relative reach of the patient (child).

The handcontrol can be reached from inside the bed through the bars and pulled so far inwards that there is a risk of strangulation.

What measures are to be taken by the addressee?

As a corrective measure, the storage location of the handswitch must be corrected.

Use the installation instructions (Appendix I) to implement the measure. The required material is available in the required quantity on request.

With this safety information you will receive a feedback form and a table with the affected serial numbers (Appendix II), which you should complete in full and return to us once the measure has been successfully implemented.

Passing on the information described here:

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

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".

Contact person:

KayserBetten GmbH & Co KG

Jens Lübben

Head of Medical Technology and Quality Management, PRRC

Phone: +49 5163 29004 14

E-mail: luebben@kayserbetten.de

ANNEX I: Assembly instructions

ANNEX II: Table of serial numbers

Installation instructions for handcontrol position



1. Position the hand control hook below the opening on the inside of the post at a height of 80 cm from the floor.



2. Screw the hand control hook in place using the enclosed screws.



3. Entfernen Sie den Aufkleber vom Pfosten.



4. Kleben Sie den beiliegenden Aufkleber wie abgebildet an den Pfosten.



5. Remove the hand control the opening in the side frame.



6. Position the wooden plug flush in the opening. Hold it in position if necessary.



7 Screw the plug in place with the enclosed screws without pre-drilling.



8. tighten the screw until the head is flush with the surface.

Feedback form

By signing this document, you confirm that you have read and understood this safety information and that the required measures have been implemented.

Company:
Address:
Contact person:
Phone: (contact person)
e-mail: (contact person)
Date:
Signature:

Please confirm in the following table (see ANNEX II) for which KayserBetts you have successfully carried out the measure and which are no longer in the field. KayserBetts that are not included in the list but are still in use, please enter at least the serial number in the table.

In order to finalise the measure, it is essential that the feedback form and the table (ANNEX II) are completed in full.

This will make it easier for you and us to retrofit all affected beds in the field and avoid unnecessary queries on our part.

Please complete and return the feedback form and the table (ANNEX II) to us.

E-mail: medizintechnik@kayserbetten.de

Fax: 05163 2076

Pattern:

ANNEX II - ID 00000

OK	a.B.	Serial no.	Order No.	Commission
<input type="checkbox"/>	<input type="checkbox"/>	SN000001	18/00000	Sample man 1
<input type="checkbox"/>	<input type="checkbox"/>	SN000002	21/00000	12345

...

...

OK Action successfully completed.

a.B. Out of service, bed is no longer in the field.

Seriennummer	Produkt
SN 017071	KB Olaf 98 natur 200/90
SN 018594	KB Olaf 135 22 Variante
SN 019400	KB Olaf 135 natur 200/90
SN 019503	KB Olaf 135 natur 200/90
SN 019716	KB Olaf 98 natur 200/90