20.10.2026

[Name]
[Additional information]
[Street]
[Postcode/ City]
[Country]

Urgent Field Safety Notice (DK) English Version

Recall of mattress extensions

Sender:
Funke Medical GmbH, Ährenfeld 10, 46348 Raesfeld, Germany
SRN: DE-MF-00007784
Referenznummer des Herstellers: R-2026-10-05

Recipients:
Specialist dealers, distributors, healthcare institutions/users

Identification of the affected medical devices:

- All mattress extensions manufactured and distributed from 2020 onwards (as accessories for medical mattresses) for insertion into beds, consisting of a cover and foam core
- REF numbers:

Item
MA14EXT**CL**0832
MA14EXTCL0851
MA14EXTCL0852
MA14EXTCL0902
HF+EXTCL-8520

The above-mentioned items have an identical foam core. The **CL** models (clinic) have a cover with a zip overlap; the covers of the **HC** models (homecare) have an exposed and visible zip.
The extensions differ in width/height and length.

Description of the problem, including the identified cause:
During a review, it was found that the products had not been classified for regulatory purposes as accessories for medical devices and had been distributed without the correct label and without a compliant IFU, which may lead to errors in use, e.g. a risk of body parts becoming trapped.

All mattress extensions distributed since 2020 are being recalled and replaced with new, correctly labelled extensions. You will receive the new IFU in advance.

What actions must be taken by the recipient?
Actions to be taken when distributed via specialist dealers/distributors:
Forwarding to healthcare institutions/users:
Please ensure within your organisation that all users of the above-mentioned products and any other persons who need to be informed are made aware of this Urgent Field Safety Notice.
Please inform your customers about the recall of the existing mattress extensions and their replacement with new, correctly labelled items.

Please forward the new enclosed IFU to your customers in advance.

As soon as the existing mattress extensions have been replaced with new mattress extensions, please destroy the old mattress extensions (e.g. via household waste through a local waste disposal company) or have your customers confirm the destruction of the mattress extensions. Please do not return them to the manufacturer.

If stock is held:
Please quarantine any stock held, if applicable.

Completion of the actions:
You will receive new, correctly labelled replacement products as soon as possible. Our sales team will contact you regarding this. Afterwards, please return the completed enclosed response form to us.

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

For healthcare institutions/users:
Please follow the instructions of your dealer.

Please read carefully the instructions for use for the mattress extensions sent to you in advance and pay particular attention to the warnings regarding correct insertion and correct fit in the bed. You will receive new, correctly labelled mattress extensions through your dealer.

Please destroy the old items yourself in consultation with your dealer or return them to your dealer for destruction.

Schedule:
Contacting specialist dealers and distributors incl. sending the IFU, calendar weeks 43/44
Replacement production and dispatch of the new items by calendar week 49
Responses via response form, calendar weeks 50/51

Communication of the information described here
Your national authority was informed of this action in advance and has received a copy of this Urgent Field Safety Notice.

Contact person:
Funke Medical GmbH, Germany

Phone: +49 (0) 2865 266 93 50

E-Mail: qm@funke-medical.de

[Name]
[Additional information]
[Street]
[Postcode/ City]
[Country]

Response form

Urgent Field Safety Notice

Recall of mattress extensions (DK) English Version

Sender:
Funke Medical GmbH, Ährenfeld 10, 46348 Raesfeld, Germany
SRN: DE-MF-00007784
Referenznummer des Herstellers: R-2026-10-05

Responding party:

☐ Specialist dealers	☐ Distributors	☐ Healthcare institutions	☐ Users

Number of destroyed mattress extensions (units) – manufactured from 2020

Item	Quantity (units)
MA14EXTCL0832	
MA14EXTCL0851	
MA14EXTCL0852	
MA14EXTCL0902	
HF+EXTCL-8520	

I/We hereby confirm that the above-mentioned items have been destroyed in the quantity entered.

Date	Name / Signature

Please return to qm@funke-medical.de