

Important Product Information

Commercial name of the affected product: Patient Support Slings, Vests, Pants, and Sheets

Field Action Identifier: FA-2022-056

Manufacturer: Liko AB (Single Registration Number: SE-MF-000001404)

Type of Action: Important Product Information

05 January 2023

Dear Sir/Madam,

Problem Description Hillrom a Baxter company is issuing this Important Product Information because we were made aware that several models of slings, vests, pants, and sheets have been manufactured and sent to customers without CE mark on their labels.

The affected products were distributed between October 11, 2019, and September 20, 2022.

The CE Mark is present within the Instructions For Use for the impacted devices.

Affected Product Refer to Attachment #1 for the product codes involved

Hazard Involved There is no safety risk associated to this issue. The omission of the CE mark on the product does not pose a hazard for patients. The characteristics of the devices have not changed, nor has the risk profile changed. In addition, the CE Mark is present within the IFU of the impacted devices.

Action to be taken by the user Baxter is kindly asking that you take the following actions:

1. Complete the enclosed customer reply form and return it to Baxter within two weeks by e-mailing it to uk_shs_fca@baxter.com, even if you do not have any inventory. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices. **This step is required, per regulatory authorities.**

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.



2. If you are a dealer, wholesaler, or distributor/reseller that distributed any product to other facilities, please notify your customers of this communication in accordance with your customary procedures.
3. If you purchased this product from a distributor, please return their reply form according to their instructions

**Further
information and
support**

For general questions regarding this communication, contact Baxter at uk_shs_fca@baxter.com

Any quality problems experienced with the use of these products may be reported using one of the following options:

Reporting product quality complaints:
HRC_UKCustomerCare@baxter.com

We apologize for any inconvenience this may cause you and your staff.

Sincerely,

Darren Blewitt
Head of Strategic Accounts UKI
Care Solutions
Baxter Healthcare Limited

Attachment 1: Affected Product Table
Attachment 2: Customer Reply Form



Attachment 1: Affected Product Table

Product Code	Product Name
3522306	SILHOUETTESLING 22 L
3522603	SILHOUETTESLING 22 XS
3522604	SILHOUETTESLING 22 S
3522605	SILHOUETTESLING 22 M
3526118	SOFT ORIG.HB SLING 26 PES XXL
3526813	SOFT ORIG.HB SLING 26 TEDDY XS
3526814	SOFT ORIG.HB SLING 26 TEDDY S
35300304	COMFORTSLING PLUS 300 MESH S
35300305	COMFORTSLING PLUS 300 MESH M
35300306	COMFORTSLING PLUS 300 MESH L
35300307	COMFORTSLING PLUS 300 MESH XL
35300325	COMFORTSLING PLUS 300 MESH M
35310305	COMFORTSLING PLUS 310 PL.NET M
35310306	COMFORTSLING PLUS 310 MESH L
35310307	COMFORTSLING PLUS 310 MESH XL
35310405	COMFORTSLING PLUS 310 PL.NET M
35350304	COMFORTSLING PLUS 350 MESH S
35350305	COMFORTSLING PLUS 350 MESH M
35350306	COMFORTSLING PLUS 350 MESH L
35350307	COMFORTSLING PLUS 350 MESH XL
35350325	COMFORTSLING PLUS 350 MESH M
35360305	COMFORTSLING PLUS 360 MESH M
35360306	COMFORTSLING PLUS 360 MESH L
35360307	COMFORTSLING PLUS 360 MESH XL
35360405	COMFORTSLING PLUS 360 PL.NET M
3540134	HYGIENESLING 40 PES S
3540135	HYGIENESLING 40 PES M
3540136	HYGIENESLING 40 PES L
3541133	HYGIENESLING 41 PES XS
3541813	HYGIENESLING 41 TEDDY XS
3545134	HYGIENESLING 45 PES S
3545135	HYGIENESLING 45 PES M
3545136	HYGIENESLING 45 PES L
3545137	HYGIENESLING 45 PES XL
3546813	HYGIENESLING 46 TEDDY XS
3550113	HYGIENEVEST 50 PES XS
3550114	HYGIENEVEST 50 PES S
3550115	HYGIENEVEST 50 PES M
3550116	HYGIENEVEST 50 PES L
3550117	HYGIENEVEST 50 PES XL
3550118	HYGIENEVEST 50 PES XXL
3550119	HYGIENEVEST 50 PES XXXL
3550812	HYGIENEVEST 50 TEDDY XXS
3550813	HYGIENEVEST 50 TEDDY XS
3555112	HYGIENEVEST HB 55 PES XXS
3555113	HYGIENEVEST HB 55 PES XS
3555114	HYGIENEVEST HB 55 PES S
3555115	HYGIENEVEST HB 55 PES M
3555116	HYGIENEVEST HB 55 PES L
3555117	HYGIENEVEST HB 55 PES XL
3555812	HYGIENEVEST HB 55 TEDDY XXS
3555813	HYGIENEVEST HB 55 TEDDY XS
3560113	MASTERVERST 60 PES XS

Product Code	Product Name
3560114	MASTERVERST 60 PES S
3560115	MASTERVERST 60 PES M
3560116	MASTERVERST 60 PES L
3560117	MASTERVERST 60 PES XL
3560118	MASTERVERST 60 PES XXL
3560414	MASTERVERST 60 PL.NET S
3560415	MASTERVERST 60 PL.NET M
3560416	MASTERVERST 60 PL.NET L
3560812	MASTERVERST 60 TEDDY XXS
3560813	MASTERVERST 60 TEDDY XS
3564114	MASTERVERST 64 PES S
3564115	MASTERVERST 64 PES M
3564116	MASTERVERST 64 PES L
3564117	MASTERVERST 64 PES XL
3564118	MASTERVERST 64 PES XXL
3564415	MASTERVERST 64 PL.NET M
3564416	MASTERVERST FRONT CLOSURE, L
3564417	MASTERVERST FRONT CLOSURE, XL
3564813	MASTERVERST 64 TEDDY XS
3567114	VEST STANDINGSHELL 67 PES S
3567115	VEST STANDINGSHELL 67 PES M
3567116	VEST STANDINGSHELL 67 PES L
3567812	VESTSTANDINGSHELL 67 TEDDY XXS
3567813	VEST STANDINGSHELL 67 TEDDY XS
3567814	VEST STANDINGSHELL 67 TEDDY S
3570114	AMPUTEESLING 70 PES S
3570115	AMPUTEESLING 70 PES M
3570116	AMPUTEESLING 70 PES L
3570314	AMPUTEESLING 70 PES MESH S
3570315	AMPUTEESLING 70 PES MESH M
3570316	AMPUTEESLING 70 PES MESH L
3575114	AMPUTEESLING HB 75 PES S
3575115	AMPUTEESLING HB 75 PES M
3575116	AMPUTEESLING HB 75 PES L
3575117	AMPUTEESLING HB 75 PES XL
3575315	AMPUTEESLING HB 75 PES MESH M
35920328	ULTRA LIFTPANTS 920 MESH XXL
35920329	ULTRA LIFTPANTS 920 MESH XXXL
3592324	LIFTPANTS 92 PES MESH S
3592325	LIFTPANTS 92 PES MESH M
3592326	LIFTPANTS 92 PES MESH L
3592327	LIFTPANTS 92 PES MESH XL
3592823	LIFTPANTS 92 TEDDY XS
3593115	SAFETYVEST 93 PES M
3593116	SAFETYVEST 93 PES L
3595414	COMFORTVEST 95 PL.NET S
3595415	COMFORTVEST 95 PL.NET M
3595416	COMFORTVEST 95 PL.NET L
3595417	COMFORTVEST 95 PL.NET XL
3683105	LIFTSHEET OCTO PES M
3683106	LIFTSHEET OCTO PES L
3683405	LIFTSHEET OCTO PL.NET M
3683406	LIFTSHEET OCTO PL.NET L



ATTACHMENT 2: CUSTOMER REPLY FORM

(IMPORTANT PRODUCT INFORMATION LETTER FA-2022-056 DATED 05 JAN 2023)

Product Name: Patient Support Slings, Vests, Pants, and Sheets
Product code: Refer to Attachment #1 for the product codes involved

Please complete and return one copy of this form per facility e-mail to uk_shs_fca@baxter.com as confirmation that you have received this notification.

Facility Name and Address: <i>(Please Print)</i>	
Reply Confirmation Completed By: <i>(Please Print Name)</i>	
Title: <i>(Please Print)</i>	
Email and/or Telephone Number (Including Area Code):	

Signature/Date: REQUIRED FIELD	<hr/>
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Your signature above indicates understanding of the contents of the attached letter, that you performed the actions outlined and disseminated this information to your staff, other services and facilities and customers, as applicable.