Rev 1: September 2018
FSN Ref: FSN24-001 FSCA Ref: n/a

Date: 09-sep-2024

Urgent Field Safety Notice
CloudCuddle Junior

For Attention of*: All customers who received a CloudCuddle Junior produced between 27-05-2024 and 30-08-2024. A list of all customers is available at Human Protection.

Contact details of local representative (name, e-mail, telephone, address etc.)*
[redacted]

CloudCuddle

Rev 1: September 2018
FSN Ref: FSN24-001 FSCA Ref: n/a

Urgent Field Safety Notice (FSN)
CloudCuddle Junior
Possible wrong installation buckles

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	CloudCuddle Junior. CloudCuddle is a bed tent designed for mentally or physically disabled people who need a heavy bed construction to keep them in bed safely during nighttime. It is delivered non-sterile
1.	2. Commercial name(s)
	CloudCuddle Junior
1.	3. Unique Device Identifier(s) (UDI-DI)
	8719325611625
1.	4. Primary clinical purpose of device(s)*
	The CloudCuddle is intended to be used for soothing and shielding bed security for children and adults who, due to physical and/or mental limitations, may unintentionally get out of bed or fall out.
1.	5. Device Model/Catalogue/part number(s)*
	CCJ01
1.	6. Software version
	n/a
1.	7. Affected serial or lot number range
	All CloudCuddle Juniors produced between 27-05-2024 and 30-08-2024
1.	8. Associated devices
	n/a

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	As a result of the manufacturing error, there is a change that the buckles on the straps that pass under the mattress have not been properly attached.
2.	2. Hazard giving rise to the FSCA*
	Because only some of the buckles might be installed the wrong way around, it is not ensured that all buckles stay fixed.
2.	3. Probability of problem arising
	Probability: 1: Improbable - Improbable that it will happen (less than once every 100.000 uses)
2.	4. Predicted risk to patient/users
	Severity: 3 - Results in injury or impairment requiring medical or surgical intervention Probability: 1: Improbable - Improbable that it will happen (less than once every 100.000 uses) Risk: 31 = Acceptable
2.	5. Further information to help characterise the problem
	n/a
2.	6. Background on Issue
	As a result of this issue, a CAPA has been initiated. The following root cause analysis has been determined from the root cause analysis, using the 'five times why method': When transferring from the old production location to the new production location, work

	instructions and quality control forms were adopted and revised. The old work instructions and quality control forms did not include correct installation of the buckles. For that reason, they have not become part of the work instructions and quality control forms at the new production location. Because the correct method of installing the buckles was not part of the instruction and final inspection, the error could arise and go unnoticed in the production process. The problem is only discovered when the product is installed. Upon installation, the problem is immediately and clearly detectable, as the straps cannot be pulled tight. If the straps can't be pulled tight, this would be obvious to the user. The IFU states: "Tilt the mattress to fasten the tensioning straps under the mattress. The tensioning strapsare fitted with buckles. Tighten the straps until taut by tightening the loose end(protruding from the snap buckle)". In the IFU is written that if a defect is suspected, the user needs to contact the manufacturer. The IFU also indicated that agitation or distress is one of the contra-indications.
2.	7. Other information relevant to FSCA
	n/a

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User***	
	☒ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☒ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Written instructions have been sent to all involved to identify the incorrect buckles on the CloudCuddle and to independently replace the buckle(s) in question so that they are installed correctly again. To support this written instruction, a recorded video was also sent to all involved, visually explaining the adjustment. When sharing the instruction, we request that each customer send us confirmation that the necessary adjustments have been made or have been found unnecessary. Weekly, we will follow up on requests towards customers where no response has yet been received. This follow-up will preferably be done by telephone. By 11-10-2024, we would like to have received confirmation from all customers.	
3.	2. By when should the action be completed?	The action must be carried out immediately by those involved. All those involved have been asked to inform us when the action has been completed. By 11-10-2024, we would like to have received confirmation from all customers.
3.	3. Particular considerations for: n/a Is follow-up of patients or review of patients' previous results recommended? No n/a	

3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes

3. 5. Action Being Taken by the Manufacturer

☐ Product Removal ☐ On-site device modification/inspection
☐ Software upgrade ☐ IFU or labelling change
☒ Other ☐ None

We have taken the following immediate measures:

- Immediately after we became aware of the problem, all products from the relevant production period were identified.
- The entire stock of finished products that have not yet been placed on the market and semi-finished products have been checked for the presence of incorrectly installed buckles. Corrections have been made where necessary to ensure that all stock consists of buckles that have been properly installed;
- The relevant work instruction for installing the buckles has been adjusted to ensure that the buckles are installed correctly in production.
- In the quality control of the final product, a control step has been added in which the correct installation of the buckles is checked.
- All employees involved have been trained in the adjustments in the above-mentioned documents. A registration (including attendance list) of this training is available.

To support the customer in making any necessary adjustments independently, a written instruction has been prepared and sent out. This written instruction includes a link to a video to clarify the required adjustments.

3	6. By when should the action be completed?	11-10-2024
3.	7. Is the FSN required to be communicated to the patient /lay user?	Yes
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Yes Appended to this FSN	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	n/a
4.	**3.** For Updated FSN, key new information as follows:	
	n/a	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	n/a	
4	6. Anticipated timescale for follow-up FSN	n/a
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**CloudCuddle B.V.**
	b. Address	[redacted]
	c. Website address	
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	• Beschreibung anpassen Steckschnalle CloudCuddle Junior – DUI • Beschrijving aanpassing buckle CloudCuddle Junior – NL • Description adjustment snap buckle CloudCuddle Junior – ENG • mededeling onjuiste montage klikgesp(en) – DUI • mededeling onjuiste montage klikgesp(en) – NL • mededeling onjuiste montage klikgesp(en) - ENG
4.	10. Name/Signature	[redacted]

	Transmission of this Field Safety Notice
	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. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate)

	Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.