Rev 1: September 2018
FSN Ref: PMS 2019 03 LV WL FSN FSCA Ref: PMS 2019 03 LV WL FSCA

Date: 27-03-2019

Urgent Field Safety Notice
Wombat Living size 3

For Attention of*: National distributor

Contact details of local representative (name, e-mail, telephone, address etc.)*
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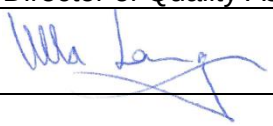
Urgent Field Safety Notice (FSN)
Wombat Living size 3
Risk addressed by FSN

1. **Information on Affected Devices***	
1.	1. Device Type(s)*
	Class 1 device Assistive ergonomic chair for disabled children
1.	1. Commercial name(s)
	Wombat Living
1.	2. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	3. Primary clinical purpose of device(s)*
	The Wombat Living is suitable for users needing a practical indoor chair, and who need extra assistance while sitting
1.	4. Device Model/Catalogue/part number(s)*
	Wombat Living size 3 Model no: 953xxx-xx and 957xxx-xx
1.	5. Software version
	N/A
1.	6. Affected serial or lot number range
	Wombat Living size 3 Manufacturing period: 09-08-2017 to 11-03-2019
1.	7. Associated devices
	N/A

2 **Reason for Field Safety Corrective Action (FSCA)***	
2.	2. Description of the product problem*
	Wombat Living has a plastic joint connecting the back to the seat base. We have received feedback from the market regarding breakage of this part whereby the back is no longer attached to the seat. In the manufacturing period 09-08-2017 to 11-03-2019 the joint was made of the plastic type ABS. Post Market Surveillance feedback prompted us to carry out a root cause analysis and testing support our conclusion that changing the material to PA6 GF30 for this particular item will improve strength and durability above the present test requirements.
2.	3. Hazard giving rise to the FSCA*
	In case of a breakage of the plastic joint, the support given to the user to obtain a correct sitting position is no longer present.
2.	4. Probability of problem arising
	Products manufactured within the stipulated timeframe meets their specification and have been tested according to state-of-the-art requirements (ISO 7176-8). Although, reports regarding actual breakages on the market have triggered preventive actions to pre-empt any adverse incidents. As a part of our general and ongoing product optimization process, alternative types of material have been evaluated and PA6 GF30 has proven to provide a better solution in this case.
2.	5. Predicted risk to patient/users
	To date no incidents involving users have been registered. The aim is to reduce the risk of this happening as far as possible – hence the ABS plastic holders on the market should be replaced as a matter of priority.
2.	6. Further information to help characterise the problem

	Replacing the plastic joint to the PA6 GF30 version will improve the probability of occurrence of a breakage.
2.	7. Background on Issue
	Feedback from the market
2.	8. Other information relevant to FSCA
	Breakage of the plastic joint between seat and back on the Wombat Living may potentially put the user at risk as the back support is no longer in place. The safety of the user is of utmost importance to us and R82 A/S has decided to make a Field Safety Corrective Action and upgrade all Wombat Living size 3 manufactured in the specified period to the current manufacturing standard.

	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 The user will be contacted by the national dealers as specified on front page		
3.	2. By when should the action be completed?	Specify where critical to patient/end user safety	
3.	3. Particular considerations for: N/A Is follow-up of patients or review of patients' previous results recommended? No		
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No	
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☒ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Replacement kits, mounting instructions and an explanatory letter will be sent out by R82 A/S to all relevant, national dealers as specified at front page of this FSN		
3	6. By when should the action be completed?	Specify where critical to patient/end user safety N/A	
3.	7. Is the FSN required to be communicated to the patient /lay user?	No	
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?		
	No Not 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 Contact details of local representative are specified on front page of this FSN	
	a. Company Name	R82 A/S
	b. Address	Parallelvej 3, DK - 8751 Gedved
	c. Website address	r82.org
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	N/A
4.	10. Name/Signature	Ulla Lange Director of Quality Assurance and Legal Affairs 

	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..*