

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

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	Director of Quality Assurance and Legal Affairs

Transmission of this Field Safety Notice	