

FSCA Ref: PMS 2019 03 NL 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.)*

Etac|R82 B.V. Tinweg 8 8445 PD Heerenveen **Email** R82nl@R82.com **Website** www.R82.nl **Phone** +31 513 68 16 86



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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. | 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. | 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. | 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 a | | | | |
| | 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. | 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 | | | | |

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| | 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 | | evice Destroy Device |
| | On-site device modification | n/inspection | |
| | Follow patient management | nt recommendations | |
| | Take note of amendment/r | einforcement of Instructions For Us | se (IFU) |
| | Other None | 9 | |
| | The user will be contacted by the national dealers as specified on front page | | |
| 3. | 2. By when should the | Specify where critica | I to patient/end user safety |
| | action be completed? | | |
| 3. | 3. Particular considerations for | or: N/A | |
| | Is follow-up of patients or r | eview of patients' previous resu | Its recommended? |
| | No | | |
| 3. | 4. Is customer Reply Require | | No |
| | (If yes, form attached specifyin | | |
| 3. | 5. Action Being Taken by | | |
| | | On-site device modification/inspective | ection |
| | Software upgrade | | |
| | | □ None | |
| | | g instructions and an explanator | |
| | | ional dealers as specified at from | |
| 3 | 6. By when should the | Specify where critical to patie | ent/end user safety |
| | action be completed? | N/A | |
| 3. | 7. Is the FSN required to be o | communicated to the patient | No |
| | /lay user? | | |
| 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 the | nis 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. | Further advice or information already expected in follow-up FSN? * | No | |
| | 5. If follow-up FSN expected, what is the further advice expected to relate to: | | |
| 4 | 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 | |
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| Transmission of this Field Safety Notice |
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