



Safety and data sheet  
Single-use bedpan

REF 16 500 21

TCE2 - The technical file is made by the manufacturer

Creation: 30.09.2016  
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- Classification of device: Class I
- Notified body number: S.O.
- Complies with the directive 93/42/CEE



OFFEC SAS - CDL (Celluloses de la Loire) - rue Pierre Clugnet - Z.I. Sainte Anne - B.P. 11 - 56350 ALLAIRE - France

<i>General description</i>	Single-use bedpan made of molded fiber	
<i>Attachments</i>	Yes	Photo
<i>Lot reference</i>	Yes	
<i>ACL Code</i>	/	
<i>Device connected</i>	No	
<i>Single use device</i>	Yes	
<i>Sterile device</i>	No	
<i>Sterilization</i>	No	
<i>Autoclavable</i>	No	
<i>Cleaning</i>	No	
<i>Unsuitable substance</i>	Fat, oil	
<i>Component parts</i>	No	
<i>Contents</i>	Cellulose	
<i>Standard</i>	PAS29 : 1999	
<i>Labeling</i>	No	
<i>Packaging</i>	Yes	Per 100 bedpans in a carton
<i>Special storage</i>	Yes	In a clean and dry place, away from humidity and heat sources
<i>Duration of use</i>	Temporary	
<i>Marking on DM</i>	No	
<i>References + extensions</i>	16 500 21	
<i>Designation</i>	Single-use bedpans	
<i>Dimensions L x B x H (mm)+- 3mm</i>	340 x 300 x 70	
<i>Thickness (mm)</i>	1.45	
<i>Capacity (ml)</i>	1500	
<i>Net weight (g)+- 1%</i>	55	
<i>Colors</i>	Natural (gray/beige)	
<i>Opening dimensions L x B (mm)</i>	210 x 255	
<i>Temperature resistance (°C)</i>	NC	
<i>Leak tightness</i>	Minimum 4 hours	
<i>Use</i>	Molded fiber disposable product intended for hygiene of patients	
<i>Instructions for use</i>	Slide the bedpan under the patient. After use, the bedpan and its content are completely disposed in macerator.	
<i>Precaution for use and/or single-use warning</i>	Leakproof product over a period of minimum 4 hours. After this time, it is recommended to empty/destroy the container to avoid any risk of leakage. Designed to slip easily under the patient, suitable for dependent patients or patients with reduced mobility. Single-use device, dispose in macerator after use .	
<i>Recycling</i>	Yes	
<i>Disposal</i>	In macerator	

Editor: Marion KLEIN  
Role: AQ  
Initials: MK

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<i>Latex/ Antistatic</i>	No/NC
<i>WEEE/REACH</i>	No/No
<i>PVC/ Phthalates</i>	No/No
<i>RoHs</i>	NC
<i>Safety data</i>	Phrases R = Null                      Combination of phrases = Null

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