

Technical Data Sheet
Furine / Furine Small

Product Name	Furine																			
Product Usage	<p>Furine / Furine Small is intended to divert faecal liquid from the rectum into a faecal collection bag (Furine Collect).</p> <p>Furine is indicated to persons with a type 6 or type 7 stool on the Bristol Stool Scale (BSS).</p>																			
Product Description	<p>Furine / Furine Small is a silicone based external Faecal Management System (FMS). It is comprised of an adhesive skin element, a silicone tube and an integrated connector and bed hanger (for connecting a Furine Collect to the FMS).</p> <p>The adhesive skin element is attached to the peri-anal skin and creates a seal against the skin. The adhesion to the peri-anal skin is achieved in combination with the use of Furine ApS's Securin Skin Barrier (see Instructions for Use).</p> <p>Furine Small is suitable to divert faecal liquid from the anal opening via the Furine tube and into a Furine Collect. Furine may remain on the perianal skin for a maximum of 7 days. Hereafter the FMS is to be replaced, and the perianal skin cleansed.</p> <p>Application: The skin is cleansed with Furine ApS's Medical Skin Wipe. Then Securin Skin Barrier is applied to the peri-anal skin and allowed to dry. Finally, Furine is applied to the peri-anal skin and a Furine Collect is attached to the connector/bed-hanger at the distal end of the tube.</p> <p>Removal: The product is removed by rinsing off Securin Skin Barrier using Furine ApS's Medical Skin Wipe. For full product understanding, read the IFU and watch illustrative videos on www.furine.com.</p>																			
Features	<ul style="list-style-type: none"> • Non-invasive • Skin friendly silicone adhesive • Soft and conformable • Strong attachment • Applicator for easy application to the peri-anal skin • Has integrated bed-hanger 																			
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Product Information	<p>Furine /Furine Small is supplied as a KIT. Apart from the product, the KIT additionally contains:</p> <ul style="list-style-type: none"> • 1 Furine Collect (ref: B10XX10) • 2 Medical Skin Wipe (ref: A00XX11) • 1 Securin Skin Barrier (B20XX10) • 1 Instructions for Use <p>For further information on these parts see their separate technical data sheets.</p>
Regulatory Information	<p>Furine / Furine Small is CE-marked in accordance with REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.</p> <p>Furine is CE-regulated as a Class 1, unsterile device.</p>
Reference Number	<p>Furine: B05XX22 / Furine Small: B135</p> <p>The reference number of Furine is country specific, and thus the "XX" changes, according to which country the product is for. For example: A Furine for England has the Product Code: B05UK22</p>
GMDN code	62038
E-class	34-38-07-01
Other Information	<p>Packaging: 1 pcs/carton Includes: 1 Furine, 1 Furine Collect, 2 Medical Skin Wipes, 1 Securin Skin Barrier, 1 Instructions for Use</p> <p>Shelf Life: 2 years</p> <p>Usage: 7 days (note, the bag is changed daily)</p> <p>Latex: All components are latex free</p> <p>Sterile: Non-sterile device</p> <p>Disposal: According to local regulations</p> <p>Country of production: Denmark Furine ApS, Industrivaenget 1, 3320 Skaevinge, Denmark</p>

