

TECHNICAL DATA SHEET

Furine® Product Family

1. Product identification

Product names	Furine® / Furine® <i>plus</i> / Furine® Small / Furine® <i>plus</i> Small
Device type	Non-invasive external fecal management system (FMS)
Manufacturer	Furine ApS, Industrivaenget 1, 3320 Skaevinge, Denmark
Product reference(s)	Furine: B05XX22 (country-specific code; "XX" is replaced by the relevant country code). Furine <i>plus</i>: B06XX22 (country-specific code; "XX" is replaced by the relevant country code). Furine Small: B135 Furine <i>plus</i> Small: B136
Device status	CE-marked medical device; non-sterile single-use device.

2. Product overview

Furine is a non-invasive external FMS applied to the perianal skin. It is designed to divert liquid fecal matter from the anal opening through a tube and into a collection bag (Furine® Collect). It is comprised of an adhesive base, a silicone tube and an integrated connector and bed hanger for connecting a Furine Collect to the FMS. The adhesive base in combination with Furine ApS Securin® Skin Barrier is adhered to the perianal skin to form a seal against the skin. The system includes an applicator to support placement of the adhesive base.

Variant-specific features:

Furine *plus* and Furine *plus* Small have an additional PE-foil layer covering around the 1.65 m silicone tube, intended to reduce odour permeation.

The Furine product family comprises standard and small versions, with and without "*plus*" in the product name. The difference between the standard and small versions is the size and dimensions of the adhesive base. Furine Small and Furine *plus* Small feature a smaller adhesive base designed for patients with smaller perianal anatomy, including children weighing 30 kg or more.

Variant	Reference No.	Large Adhesive Base (standard size)	Small Adhesive Base (for small perianal anatomy)	Tube Cover for Odor Control
Furine	B05XX22*	✓		
Furine Small	B135		✓	
Furine <i>plus</i>	B06XX22*	✓		✓
Furine <i>plus</i> Small	B136		✓	✓

* country-specific code; "XX" is replaced by the relevant country code

3. Main components and materials

Component	Material / description
Adhesive base: backing	Silicone; transparent
Adhesive base: gel adhesive	Silicone skin gel adhesive, colored blue
Tube	Silicone hose, 1.65 m; transparent
Applicator	PP (polypropylene), colored blue
Tube outlet / connector	HDPE (high-density polyethylene), natural
Latex	The current technical data sheet states that all components are latex-free .
Tube cover (Furine <i>plus</i> variants)	PE foil hose, 1.65 m; transparent.

Adhesive Base Dimensions

Variant	Outer dimensions (mm)	Opening dimensions (mm)
Furine / Furine <i>plus</i>	87.4 × 67.7	38.2 × 18.4
Furine Small / Furine <i>plus</i> Small	73.0 × 60.0	24.0 × 14.0

4. Product configuration / kit contents

Furine (all variants) is supplied in a kit containing:

- 1 × Furine-family device (variant as ordered)
- 1 × Furine Collect (ref. B10XX10, country-specific code; "XX" is replaced by the relevant country code)
- 2 × Medical Skin Wipe (ref. A00XX11, country-specific code; "XX" is replaced by the relevant country code)
- 1 × Securin Skin Barrier (ref. B20XX10, country-specific code; "XX" is replaced by the relevant country code)
- 1 × Instructions for Use (IFU)

For further information on Furine Collect, Medical Skin Wipe and Securin Skin Barrier, refer to their respective technical data sheets.

5. Use and handling information

Maximum duration of use	The Furine device may remain on the perianal skin for up to 7 days, in accordance with the IFU. Replace the device after this period.
Collection bag	Furine Collect must be replaced daily, or more frequently when needed, as stated in the IFU.
Sterility	Non-sterile. Do not sterilise.
Disposal	Dispose of used product as clinical waste in accordance with local regulations.
Storage	Storage at 5 °C to 30 °C.
Shelf life	2 years.

6. Regulatory and classification information

Regulatory framework	Furine 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.
Classification	Class I, non-sterile.
GMDN code	62038.
E-class	34-38-07-01.
Intended users	Trained medical professionals in a healthcare setting, as stated in the current IFU.

7. Instructions for use and safety information

This technical data sheet is supplementary product information and does not replace the Instructions for Use. For the intended purpose, indications, contraindications, warnings, precautions, application, maintenance, removal and other safety information, consult the current IFU supplied with the device.

8. Document control

Document title	Technical Data Sheet – Furine Product Family
Document number	DMR-B05-2001-03
Revision / date	2026-10-21
Supersedes	Existing Furine data sheets: DMR-B05-2001-02, dated 2024-06, DMR-B06-2001-02, dated 2024-06, DMR-B135-2001-01, dated 2026-02, DMR-B136-2001-01, dated 2026-09
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