

# Technical Data Sheet (TDS)

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## Product: Medena Bend Continent Ileostomy Catheter 68732

### 1. Product Identification

Product Name / Model	Medena Bend Continent Ileostomy Catheter
Article Number	68732
Intended Use / Application	Designed for catheterization of continent ileostomy such as Kock Pouch (K-Pouch) or Indiana Pouch.
Manufacturer	YourRad AB, Sweden (ISO 13485 certified)
Origin / Development	Originally developed by AstraTech (Sweden) in collaboration with surgeons and stoma care nurses. Manufacturing transferred to YourRad AB in 2022.
Regulatory Classification	Class I Medical Device under EU MDR 2017/745, Rule 5, Annex VIII, Chapter III
Basic UDI	735014646006873EC

### 2. Material Composition

Component	Material	Grade / Remarks
Catheter tube	Medical-grade PVC (Polyvinyl Chloride)	Contains TEHTM (phthalate-free plasticizer), biocompatibility confirmed per ISO 10993 and USP Class VI
Surface finish	Smooth, rounded tip with ventilation hole	Designed to minimize trauma to stoma tissue and allow gas release
Drainage holes	Two lateral holes	Optimized distance and size to prevent bending or collapse
Colorant / additives	None declared	—
Biocompatibility	Confirmed	Compliant with ISO 10993 and USP Class VI

### 3. Thermal & Environmental Performance

Operating Temperature Range	Ambient to body temperature (~10–40 °C)
Storage Temperature	5–30 °C (recommended)
Shelf Life	3 years from date of manufacture
Chemical Resistance	Resistant to urine and common disinfectants (PVC-based)

### 4. Functional Characteristics

- Rounded tip reduces risk of mucosal irritation.

- Gas release hole minimizes internal pouch pressure.
- Twin side holes ensure smooth drainage and reduce kinking.
- Smooth surface allows easy insertion and removal.

### 5. Safety & Biocompatibility

Cytotoxicity, Sensitization, Irritation	Confirmed per ISO 10993-5 and -10
Material Safety	PVC with TEHTM is DEHP-free and compliant with EU MDR, ISO 10993, and USP Class VI
Residuals / Leachables	Within limits per ISO 10993-18

### 6. Handling, Storage & Packaging

- Store in original packaging at 5–30 °C, away from direct sunlight.
- Avoid excessive bending or mechanical stress.
- Discard after use per local regulations for medical waste.
- Only to be used after training by a qualified stoma care nurse.
- Packaging Information: Transportation package contains 150 catheters.