Product Specifications Sheet

Specification Sheet No	SSN-JFRU06-005		
Product Name	Bile Bags		
Product Description	Bile Bags 500ml Ryles/Kehrs Fitting		
Range	Universal		
Manufacturer	Romsons International		
Material	Poly Vinyl Chloride		
Sterilisation	EO Sterile		
Issue Date	21st May 2024	**Version No**	R02



Intended use	Intended for the collection and storage of bile and other gastric secretions.

Packaging							
Product Code	Volume	PVC Bag L x W (Approx.)	Diameter of connector	Length of Tapper Connector	Length of Outlet tubing with connector	Items Per Pack	Qty – Shipper Carton
UN405RK	500 ml	250 x 120 mm	2.70mm± 0.5mm	55mm± 2mm	100mm± 5mm	1	50

Quality Certification	ISO 13485:2016		
Device Classification	Class Is	**Rule**	1
Conformity Route	Medical Devices Directive (93/42/EEC)		
Storage conditions	Store in a cool dry place away from heat and direct sunlight		
Shelf life	5 Years from manufacturing date if stored as recommended		
Contraindications/Warnings	To be used by a qualified / a well-trained medical person. Make sure tap is closed before use. Carefully read all instructions prior to use. Observe all warnings & precautions noted throughout these instructions. Failure to do so may result in complications.		
Markings	Universal Logo, Ref, Product name, Lot, Quantity, Barcodes, Manufacture date, Expiry date, CE Mark, Single use, Do not re-sterilise, Latex free, EO -sterile, Medical device, Do not use if package is damaged, keep dry, keep away from sunlight, Manufacturer Name & Address, Distributor contact, Non-pyrogenic, IFU, Caution, One-way Valve, DEHP Free, Graduation marking		
Additional information	Product is Latex free. Product is fitted with Multi-Purpose Ryles / Kehrs Tube Fitting and T type Drainage tap.		
Medical Device and Reporting System: Incidents caused by this device must be reported immediately to our offices.			

The information provided within this Specification Sheet is correct as of last revision but it is subject to change without notice.

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Amendment Record

This procedure is reviewed to ensure its continuing relevance to the system and process that is describes. A record of contextual additions or omissions is given below. This revision history lists all changes to this document, the date of each revision, and the reason for each revision.

Revision Number	Revision Date	Reason for Revision	Updated by
R01	16/01/2023	New SSN Mediq Healthcare UK brand Template	Elizabeth Ogunkolade
R02	21/05/2024	Update Mediq Healthcare UK address	Jack Wong

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