Product Specifications Sheet

Specification Sheet No	SSN-JFRU06-012		
Product Name	Bile Bags		
Product Description	Bile Bag - 350ml with Wide Bore Connector		
Range	Universal		
Manufacturer	Romsons International		
Material	Polyvinyl Chloride		
Sterilisation	EO-sterile		
Issue Date	22 April 2024	**Version No**	R01



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

Packaging							
Product Code	PVC Bag dimension (approximately)		Length of Tapper Connector	Inside Diameter of connector	Length of Outlet tubing with connector	Items Per Pack	Qty – Shipper Carton
	Length (mm)	Width (mm)					
UN400WB	250	100	55±2mm	5±0.5mm	100±5mm	1	50

Quality Certification	ISO 13485:2016		
Device Classification	Class Is	**Rule**	1
Conformity Route	Medical Devices Regulation (EU) 2017/745		
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	Carefully read all instructions prior to use. Observe all warnings & precautions noted throughout these instructions. To be administered by an expert qualified medical professional. For Single Use Only. Maximum use period not more than 7 days		
Markings	Universal Logo, Ref, Product name, Lot, Barcodes, Expiry date, CE Mark, Latex free, EO-sterile, Do not re-sterilize, DEHP free, Medical device, Single use, keep dry, keep away from sunlight, Consult Instructions for Use, Non-pyrogenic, One-way Valve, Contents sterile until opened, damaged or wet, Do not use if the packaging is damaged. Manufacturer Name & Address, EC-REP, Distributor contact		
Additional information	Product is Latex-free, Non-Toxic, and Pyrogen Free. Fitted with Multi-Purpose Wide Bore connector. T type Drainage tap Bile Bag has Graduation from 25ml to 350ml.		
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	22/04/2024	New SSN Mediq Healthcare UK brand Template	Elizabeth Ogunkolade

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