

Product Specifications Sheet

Specification Sheet No	SSN-JFRU06-011			
Product Name	Urine meter			
Product Description	500ml urine meter top chamber			
Range	Universal			
Manufacturer	Romsons International			
Material	PVC			
Sterilisation	EO Sterile			
Issue Date	21st May 2024	Version No	R02	

Intended use	Device intended for closed urinary drainage and concomitant hourly monitoring of the urine output in critically ill patients.
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Packaging				
Product code	Length of PVC Tube (mm)	Internal Diameter of Connector with sampling port (mm)	Capacity of measuring chamber (Urine Bag) (ml)	Qty – Shipper Carton
UN1018-250	1200±20	6±0.2	250±10 (2000±50)	30pcs
UN1018-500	1200±20	6±0.2	500±10 (2000±50)	30pcs

Quality Certification	ISO 13485:2016		
Device Classification	Is	Rule	1
Conformity Route	EU MDR 2017/745		
Storage conditions	Store in a cool dry place away from heat and direct sunlight, 5°C to 40°C		
Shelf life	5 years if stored as recommended above		
Contraindications/Warnings	Hypersensitivity to device material, Interstitial cystitis, Urinary bladder wall deformities, Thick-walled bladder. This device is intended for Single use only. Maximum use period not beyond 7 days. Do not resterilize and/or reuse the device. Do not put the Device to Use after the Use by Date or Date of Expiry.		
Markings	Manufacturing, ECREP, Medical Device, Single use only, ETO sterilization, Single Sterile barrier system, Do not re-sterilze, Instruction for Use, Keep Dry, Keep away from sunlight, Do not use if packing is damaged, Lot number, Date of manufacture, Used by date, Caution.		
Additional information	Latex free, Phthalate free Product follow ISO 8669-2 & ISO 13868 requirement. Graduation scale of Chamber - 250ml – 5, 15, 25, 50, 75, 100, 150, 200, 250 (±2%) - 500ml – 5, 10, 15, 20, 25, 50, 100, 150, 200, 250, 300, 350, 400, 450, 500 (±2%) Graduation Scale of Bag 100 to 2000ml at each 100ml gap (approximate volume)		
Medical Device and Reporting System: Incidents caused by this device must be reported immediately to our offices.			

Document Reference	Document Name	Reviewed By	Approved By	Revision Number	Issue Date
DMS 04-004	Product Specification Sheet	Jack Wong	Racheal Begg	R02	03 rd April 2024

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 it 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	21/05/2024	Update to Mediq Healthcare UK brand replacing DSN	Jack Wong
R02	21/05/2024	Update Mediq Healthcare UK address	Jack Wong

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