

Product Specifications Sheet

Specification Sheet No	SSN-JFRU06-003		
Product Name	Midstream Urine Collection		
Product Description	UN252 - Universal MSU With Funnel UN257 - Universal MSU Plastic Cone with swab UN260 - Universal MSU With Boric Acid		
Range	Universal		
Manufacturer	Romsons International (UNIT-II)		
Material	Container: Polystyrene Funnel: Polyethylene Cap: Polypropylene Wipes/ PDI Towelette: Non-woven Stopper: Polypropylene		
Sterilisation	EO Sterilisation		
Issue Date	21st May 2024	Version No	R02



Intended use	To collect midstream urine sample from hospital and home-based patients in an effective and easy manner.
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Packaging								
Product code	Colour of Cap	Wipe	Stopper	Volume (ml)	Chamber Height (cm)	Chamber diameter (cm)	Qty- Inner	Qty – Shipper Carton
UN252	White	/	/	20	9	2.5	1	100
UN257	White	Yes	/					100
UN260	Red	/	Yes					80

Quality Certification	ISO 13485:2016		
Device Classification	Class Is	Rule	4
Conformity Route	Medical Device 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	Always refer to instructions before use.		
Markings	Universal Logo, Ref, Product name, Lot, Quantity, Barcodes, EC-REP, EO Sterile, Do not resterilise, Manufacturing date, Expiry date, CE Mark, Single use, Latex free, Medical device, Do not use if package is damaged, keep dry, keep away from sunlight, Consult Instruction for use, Manufacturer Name & Address, Distributor contact		
Additional information	Latex free and sterile		
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	Ashley Miller	Racheal Begg	R01	12 th June 2023

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	10/10/2023	New SSN to Mediq Healthcare UK brand template	Elizabeth Ogunkolade
R02	24/04/2024	Changed from MDD (93/42/EEC) to MDR 2017/745	Elizabeth Ogunkolade
R03	21/05/2024	Update Mediq Healthcare UK address	Jack Wong

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