Product Specifications Sheet

Specification Sheet No	SSN-JFRU06-009		
Product Name	Misc / Supplementary Items		
Product Description	Surgical Skin Marker		
Range	Universal		
Manufacturer	Romsons Group Private Limited		
Material	Polyester, PET, Gentian Violet, Polypropylene, Master Batch.		
Sterilisation	EO Sterile		
Issue Date	21st May 2024	**Version No**	R02



Intended use	Surgical Skin Marker Pen with Ruler is a specific type of pen used to outline/mark the surgical incision site on the skin for surgery preparation. Ruler is packaged with skin marker is not measuring device and should be used as an indicator only

Packaging								
Product Code	Colour	Skin Marker (mm) approx.		Ruler (mm) approx.		Items Per Pack	Qty-Inner	Qty – Shipper Carton
		Outer dimension	Length	Length	Width			
UN65-B	Violet	10	132	152	20	1	50	900

Quality Certification	ISO 13485:2016		
Device Classification	Class Is	**Rule**	2
Conformity Route	Medical Devices Directive (93/42/EEC)		
Storage conditions	Store in a cool dry place away from heat and direct sunlight between 5°C - 40°C		
Shelf life	3 Years from manufacturing date if stored as recommended		
Contraindications/Warnings	Carefully read all instructions prior to use. To be administered by a professionally competent, qualified / a trained paramedic person. Not to be used in patients with known hypersensitivity to any of the materials used or allergy to Gentian Violet (crystal violet) dye, Skin Allergy, Burns and Wounds. Not to be used on broken skin Cap the Surgical marker and keep the marker in horizontal position.		
Markings	Universal Logo, Ref, Product name (in English and other 22 languages), Lot, Quantity, Barcodes, Manufacture date, Expiry date, CE Mark, Single use, Do not re-sterilise, Latex free, EO-sterile, Single Sterile barrier system, Temperature limit (5°C - 40°C), IFU, Medical device, Non-pyrogenic, Do not use if package is damaged, keep dry, keep away from sunlight, Manufacturer Name & Address, Distributor contact, EC-REP		
Additional information	Product is packed in a peelable blister pack per unit. Product is Latex-free		
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	15/03/2024	New SSN Mediq Healthcare UK brand Template	Elizabeth Ogunkolade
R02	21/05/2024	Update Mediq Healthcare UK address	Jack Wong

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