

# Product Specifications Sheet

<b>Specification Sheet No</b>	SSN-JFP002-001			
<b>Product Name</b>	Curette Dermal			
<b>Product Description</b>	Curette Dermal			
<b>Range</b>	365 Healthcare			
<b>Manufacturer</b>	Paramount Surgimed Ltd.			
<b>Material</b>	Blade – 304 Stainless Steel Handle – ABS Protective Cap - LDPE			
<b>Sterilisation</b>	Non-Sterile			
<b>Issue Date</b>	21st May 2024	<b>Version No</b>	R02	

<b>Intended use</b>	The device is used for scraping lesions from the surface of a patient's skin. The device is invasive device and for transient use.
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Packaging				
Product code	Size (mm)	Items Per Pouch	Qty- Inner	Qty – Shipper Carton
365DCP40	4	1	10	250
365DCP70	7	1	10	250

<b>Quality Certification</b>	ISO 13485:2016			
<b>Device Classification</b>	Class IIa	<b>Rule</b>	6	
<b>Conformity Route</b>	Medical Devices Directive (EU) 93/42/EEC Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)			
<b>Storage conditions</b>	Keep away from direct sun light. Storage temperature should be 10 to 40 degree Celsius. Humidity of storage area should be 35% RH to 65% RH. Store in cool and dry place.			
<b>Shelf life</b>	5 years if stored as recommended			
<b>Contraindications/Warnings</b>	None known			
<b>Markings</b>	Ref Code, Quantity, Product name, Matrix codes, Lot, Manufacturing & Expiry date, CE Mark, Single use, Latex free, Medical device, Non-Sterile, keep dry, keep away from sunlight, EC-REP, Manufacturer name and address			
<b>Additional information</b>	Product is latex free			
<i>Medical Device and Reporting System: Incidents caused by this device must be reported immediately to our offices.</i>				

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



## 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	04/10/2023	Update to Mediq Healthcare UK brand template	Jack Wong
R02	21/05/2024	Update Mediq Healthcare UK address	Jack Wong

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DMS 04-004	Product Specification Sheet	Jack Wong	Racheal Begg	R02	03 <sup>rd</sup> April 2024