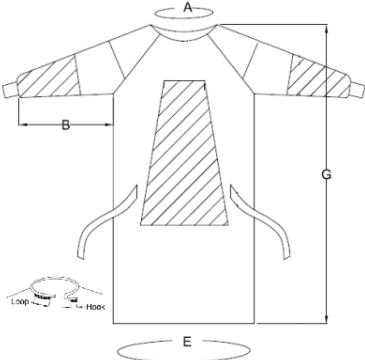


Product Specifications Sheet

Specification Sheet No	SSN-FT1358-008		
Product Name	Surgical Gowns		
Product Description	Zone Reinforced Arthroscopy Surgical Gown		
Range	365 Healthcare		
Manufacturer	Sino Protection (Hefei) Medical Products Co., Ltd		
Material	Gown: Blue AS + AR SMMMMS Wrap: Blue SMS Reinforcement: SPP+PE laminated Towel: Polyester scrim		
Sterilisation	EO Sterile		
Issue Date	08 th April 2025	Version No	R02



A = Neck Circumference
B = Sleeve Length
E = Gown Circumference
G = Gown Length

Intended use	Intended to be used to prevent cross contamination between patients and end user
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Packaging							
Product code	Size	A (cm) +2/-0	B (cm) +0/-2	E (cm) +2/-0	G (cm) ±2	Qty- pc/bag	Qty – pc/box
40-23ZR365	Large, Extra Long	65	62	156	151	1 x Sterile Gown – Colour Blue, 1 x SMS Wrap,	30
40-24ZR365	Extra Large, Extra Long		65	176		2 x Hand towel	

Quality Certification	ISO 13485:2016		
Device Classification	Class Is	Rule	1
Conformity Route	Medical Devices Directive 93/42/EEC		
Storage conditions	Store in a cool dry place away from heat and direct sunlight		
Shelf life	5 years if stored as recommended		
Contraindications/Warnings	No Known		
Markings	365 Logo, Ref, Size, Product name, Product list, Image, Quantity, EN 13795-1:2019, Zone reinforced protection: ZR, Barcode, NAFDAC number, Lot, Manufacture date, Expiry date, CE Mark, Single use, Latex free, Medical device, Sterile EO, Do not use if package is damaged, keep dry, keep away from sunlight, Manufacturer name & Address, EC-REP		
Additional information	This product conforms to standard EN 13795-1:2019 and 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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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



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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	04/10/2024	1 st version	Jack Wong
R02	08/04/2025	Update dimension	Jack Wong

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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 rd April 2024