

Product Procedure Specifications Sheet

Specification Sheet No	SSN-FT1390-008		
Product Name	Maternity Pack		
Product Code	36551706 (Rev11)		
Range	365 Healthcare		
Manufacturer	Wujiang Kangxin Surgical Dressings Co. Ltd		
Packaging	50 pieces per carton		
Sterilisation	EO Sterile		
Issue Date	25th September 2024	Version No	R01a



Intended use	Intended to be used to provide the essential items required for childbirth and post-natal treatment.
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Pack content				
Item	Product code	Quantity	Dimensions	Material
Yellow Waste Bag	2001	1	35x45cm	High-density polyethylene
White Label	2851	1	7x9cm	Paper with adhesive underside
Apron White PE	3008	3	80x140	Low Density Polyethylene / Plastic
White Umbilical Cord Clamp	4802	4	5cm	Polyformaldehyde
Umbilical Cord Scissors	5913	2	10cm	Stainless Steel A.I.S. I 420
A5 Insert Sheet A5	8123	1	140x210mm	Coated paper
Blue Tissue Backed Drape PE (SF)	8812	6	55x70cm	Pulp Tissue + Film Lamination
White Gauze Swabs 12ply XRD	10204	2	10x10cm	Cotton yarn with XRD thread
Absorbent Pad Blue & White	12701	6	40x60cm	Non-woven + wood pulp + fluff pulp + PE film
Baby Hat	14901	1	11.5x15cm	Pure Cotton
Large Baby Hat	14902	1	13.8x18cm	Pure Cotton
Baby ID Band	15101	1	170x18mm	Poly Vinyl Chloride+ paper card
Adult ID Band	15102	1	250x25mm	Poly Vinyl Chloride+ paper card
Newborn Nappy/Diaper	15201	1	13.5x16cm (+/-0.5)	Non-woven+ SAP+ Wood/Fluff Pulp+ PE Film
Self-Seal Poly Bag	15301	1	40x30cm	Low density polyethylene

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

Quality Certification	ISO 13485:2016		
Device Classification	Class IIa	Rule	Article 52
Conformity Route	Medical Devices Regulation (EU) 2017/745 Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)		
Storage conditions	Store in a cool dry place away from heat and direct sunlight.		
Shelf life	Refer to product packaging		
Contraindications/Warnings	None		
Markings	365 Healthcare logo, product reference, product name, Pack contents, Quantity, manufacture date, expiry date, lot number, barcode, single use only symbol, latex free symbol, medical device symbol, sterilised by ethylene oxide symbol, do not re-sterilise, do not use if packaging is damaged symbol, CE mark, keep dry symbol, keep away from sunlight symbol, manufacture name and address, EC rep details, Distributor name and address		
Additional information	This product is latex free. Do not use if the packaging is damaged. Product sterilised with ethylene oxide.		
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 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
R01a	25/09/2024	Update to Mediq Healthcare UK brand replacing DSN856	Elizabeth Ogunkolade

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