

Product Procedure Specifications Sheet

Specification Sheet No	SSN-FT1357-012		
Product Name	Dressing Pack with Apron and Nitrile Glove		
Product Code	365-10504 365-10505 365-10506		
Range	365 Healthcare		
Manufacturer	SIMP (Shanghai ISO Medical Products Co., Ltd.)		
Packaging	240pcs per Outer		
Sterilisation	EO Sterile		
Issue Date	03 rd Oct 2024	Version No	R01



Intended use	This range consists of general supplementary items which can be used on its own or in addition to the above procedure packs for the required clinical procedure.
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Pack content				
Item	Product code	Quantity	Dimensions	Material
Gloves, walleded (only for 365-10504)	03.00.00.0023	1 pair	Small	Nitrile
Gloves, walleded (only for 365-10505)	03.00.00.0019	1 pair	Large	Nitrile
Gloves, walleded (only for 365-10506)	03.00.00.0020	1 pair	Medium	Nitrile
Apron	01.00.00.0177	1	132 X 81cm	Polyethylene / Plastic
Sterile Field	03.08.00.0027	1	50 x 50cm	20gsm PE + 25gsm Paper
White Disposable Bag	01.07.00.0303	1	45 x 26cm	HDPE

Quality Certification	ISO 13485:2016		
Device Classification	Class Is	Rule	Article 22
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	5 Years – if stored as recommended above		
Contraindications/Warnings	No Known		
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,		

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

	do not re-sterilise, do not use if packaging is damaged symbol, CE mark, keep dry symbol, keep away from sunlight symbol, manufacture address, EC rep details, Distributor address
Additional information	This product is latex free. Do not use if the packaging is damaged. Product sterilised with ethylene oxide.
<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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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	03/10/2024	1 st version	Jack Wong

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