

PRODUCT SPECIFICATION

Product name	Wound Care Pack Option II Plus
Product code	6084AF
Range	Premier
Type	Sterile
Sterilization method	EO



Pack Content	1 pair nitrile blue accelerator free gloves (medium) 5 non woven swabs (7.5 x7.5cm 4ply) 1 dressing towel 1 laminate sheet 1 two compartment tray 1 gallipot (60ml) 1 orange disposal bag 1 sterile laminate sheet
Labelling	Product name, Premier Logo, Code Ref, lot number, Expiry Date, latex free, Single use, sterility symbol and CE Marking
Packing	50 packs per outer carton

Primary use	For use in aseptic procedures and Wound Care in hospitals, community care and other areas.
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NITRILE GLOVES SPECIFICATION

Freedom from holes (BS EN455-1)	
Water tight test	General inspection level I, AQL 1.5
Force at break (BS EN 455-2)	≥ 6.0 N (during shelf life)
	≥ 6.0 N (after challenge testing)

Dimensions –BS EN 455-2	Medium
Palm width (mm)	95± 5
Length (mm)	240min

Residual powder (BS EN 455-3)	< 2 mg/glove
Residual protein	< 20 ug/g

NON WOVEN SWABS SPECIFICATION

Size	(7.5 x 7.5)cm ± 5%
Material	non woven fabric (70% viscose /30% polyester)
Colour	White
Weight/ m2	25 g/m2 ± 10%

The information provided within this Data Sheet is correct as of last revision but it is subject to change without notice.

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QUALITY STANDARDS

Quality certification	ISO 13485:2003
CE Classification	Class 1s - Medical Device Directive 93/42/EEC
Conformity to standards	The gloves confirm to BS EN455-1, 2,3 &4 The sterilization process is validated according to BS ISO11135
Storage conditions	Store in a cool dry place away from heat and direct sunlight
Shelf life	3 Years if stored as recommended above
Additional information	The product is Latex free, accelerator free. The pack remains sterile unless opened.
<i>Medical Device and Reporting System: According to the official criteria of MDD, incidents caused by this device must be reported immediately to our offices.</i>	

REVISION:	6.0	DATE	17/11/2015	AUTHOR	F Li
NOTES:	Periodic review, DSN format and Shermond logo updated.				
REVISION:	7.0	DATE	10/11/2017	AUTHOR	F Li
NOTES:	Changed to EO sterilization; changed swab spec from 30g/ m2 to 25g/ m2				

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