

PRODUCT SPECIFICATION

Product name	Nitrile Exam Gloves
Range	Premier Performer
Type	Powder free, sterile
Marking	Product name, Premier Logo, Size, Code Ref., Lot Number, Expiry date, CE Mark, sterile and single use symbols
Shape	Standard cuff length and ambidextrous.
Material	Nitrile
Colour	Blue
Sterilization method	Ethylene Oxide (EO)

Size	Length (mm) (according to EN455-2)	Palm width (mm) (according to EN455-2)	Product code
XS	240	75 ± 5	P2759/S
S	240	85 ± 5	P2760/S
M	240	95 ± 5	P2761/S
L	240	110 ± 5	P2762/S
XL	240	115 ± 5	P2763/S

Primary use	In the medical field to protect patient and user from cross-contamination when conducting medical examinations, diagnostic and therapeutic procedures and for handling contaminated medical material.
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Packaging	Dispenser box (DB) S; M; L; XL.	50	items
	Outer Carton (OC)	4	DB

This product complies with Commission Directive 2002/72/EC (contact with food)



Residual powder (according to EN 455-3)	< 2 mg/glove
Residual protein	< 20 ug/g
Residual accelerator	< 0.15%

Thickness (minimum at palm)	0.15mm
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Force at break (according to EN 455-2)	≥ 6.0 N (during shelf life)
	≥ 6.0 N (after challenge testing)

Quality certification	ISO 13485
Conformity to guidelines	Class 1s – Medical Device Directive 93/42/EEC Cat. III – Personnel Protective Equipment 89/686/EEC
Conformity to standards	EN 455 parts 1, 2, 3 & 4 for medical gloves BS EN 374-2:2003 water leak test BS EN374 -3:2003 chemical Permeation level 6 - Sodium Hydroxide 40% EN420:2003 +A1:2009 for protective gloves
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	Finger textured, single chlorinated and polymer coated gloves to provide excellent reliability. Latex free.

Medical Device and Reporting System:

According to the official criteria of MDD, incidents caused by this device must be reported immediately to our offices.

REVISION:	3.0	DATE	14/03/2016	AUTHOR	J Bertran
NOTES:	Sterilisation method, DSN format and Shermond logo updated.				

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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