

PRODUCT SPECIFICATION

Product name	Soft Vinyl Examination Gloves
Range	Premier Prestige
Type	Powder free, sterile
Marking	Product name, Premier Logo, Size, Code Ref., Lot Number, Expiry date, CE Mark and single use symbols
Shape	Standard cuff length and ambidextrous.
Material	Vinyl
Colour	Natural
Sterilization Method	Ethylene Oxide

Size	Length (mm) (according to EN455-2)	Palm width (mm) (according to EN455-2)	Product code
S	240	84 ± 3	P4301
M	240	94 ± 3	P4302
L	240	105 ± 3	P4303

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	pairs
	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)	0.15 mm
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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
Conformity to standards	EN 455 parts 1,2 & 3
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 gloves contain no latex proteins or chemical accelerators which can cause skin reactions. They are softer and more flexible than standard vinyl gloves providing a good comfort fit.

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	23/07/2015	AUTHOR	J Bertran
NOTES:	Periodic review, DSN format and Shermond logo updated.				
REVISION:	4.0	DATE	29/11/2017	AUTHOR	F Li
NOTES:	Add sterilization method EO to the data sheet				

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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