

PRODUCT SPECIFICATION

<b>Product name</b>	Nitrile Exam Gloves
<b>Range</b>	Healthgard
<b>Type</b>	Powder free, non-sterile
<b>Marking</b>	Product name, Premier Logo, Size, Code Ref., Lot Number, Expiry date, CE Mark, and single use symbols
<b>Shape</b>	Standard cuff length and ambidextrous.
<b>Material</b>	Nitrile
<b>Colour</b>	Blue

Size	Length (mm) (according to EN455-2)	Palm width (mm) (according to EN455-2)	Product code
<b>XS</b>	240	74 ± 3	PSCR0150(N)
<b>S</b>	240	84 ± 3	PSCR0151(N)
<b>M</b>	240	94 ± 3	PSCR0152(N)
<b>L</b>	240	105 ± 3	PSCR0153(N)
<b>XL</b>	240	113 ± 3	PSCR0154(N)

<b>Primary use</b>	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. Also, to reduce exposure between the wearer and external hazards such as chemicals and/or microorganisms.
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<b>Packaging</b>	Dispenser box (DB) XS;S;M;L;XL.	200	items
	Outer Carton (OC)	10	DB

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



<b>Residual powder</b> (according to EN 455-3)	< 2 mg/glove
<b>Residual protein</b>	< 20 ug/g

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

<b>Quality certification</b>	ISO 13485
<b>Conformity to guidelines</b>	Class 1 - Medical Device Directive 93/42/EEC Category III (Complex Design) - Personal Protective Equipment 89/686/ECC
<b>Conformity to standards</b>	EN 455 parts 1, 2 & 3 and 4 BS EN 374-2:2003 micro-organism hazard BS EN374 -3:2003 chemical hazard Performance level 6 - Sodium Hydroxide 40% EN420:2003 +A1:2009
<b>Storage conditions</b>	Store in a cool dry place away from heat and direct sunlight
<b>Shelf life</b>	3 Years if stored as recommended above
<b>Additional information</b>	Finger textured, single chlorinated and polymer coated gloves to provide excellent reliability.

*Medical Device and Reporting System:*

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

<b>REVISION:</b>	6.0	<b>DATE</b>	26/01/2018	<b>AUTHOR</b>	J Bertran
<b>NOTES:</b>	Product codes added/amended for the inclusion of -N.				

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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