

Technical Data Sheet



nitrylex® PF COMPLETE

PRODUCT DESCRIPTION

Type of the glove	Examination, protective, powder free, non-sterile
Material	Nitrile
Donning powder	-
Colour	Violet
Shape	Ambidextrous
Cuff	Beaded
External surface	Microtextured with additional fingertips texture
Packaging	10 x 100 pcs

PRODUCT REFERENCES

Size/ reference number	XS	RD30102001
	S	RD30102002
	M	RD30102003
	L	RD30102004
	XL	RD30102005

PHYSICAL PROPERTIES

Dimension	Size	XS (5-6)	S (6-7)	M (7-8)	L (8-9)	XL (9-10)
	Length [mm]		240	240	240	240
Width [mm]		≤80	80± 10	95± 10	110± 10	≥110
Thickness (single wall) [mm]	Middle finger				0,07	
	Palm				0,06	
	Cuff				0,05	
Elongation at break [%]	Before ageing				500	
	After ageing				400	
Force at break [N]	Before ageing				6,0	
	After ageing				6,0	
Minimum						

MANUFACTURING AND SAFETY STANDARDS

AQL (Pin-Holes)	Manufacturing final release; GL-I AQL ≤ 1,5 in accordance with test result according the procedure ISO 2859	
Protein content	Not applicable	
CE classification	Class I – Medical Device (Council Directive 93/42/EEC and Directive 2007/47/EC) Category III – Personal Protective Equipment (Council Directive 89/686/EEC) EC Type-Examination Certificate issue by SATRA Notified Body 0321	
Compliances	EN ISO 13485 EN ISO 14971 EN 455-1, EN 455-2, EN 455-3, EN 455-4 EN 980 EN 1041	EN 374-1 excluding point 5.3.2 EN 374-2 EN 374-3 EN 420 EN 388
Viral test	Passes test in accordance with ASTM F 1671	
Cytostatics permeation	Test in accordance with ASTM D 6978-05	
Chemical substances permeation	Test in accordance with EN 374-3	
Shelf life	3 years	

STORAGE

Storage instruction Keep out of direct sunlight. Store in a cool, dry place in temperature 5-30° C. Keep away from sources of ozone and ignition.

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ISO 9001:2008;
no. 93133-2011-AQ-POL-FINAS
ISO 13485:2003;
no. 93134-2011-AQ-POL-FINAS
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