

## Technical Data Sheet



### nitrylex® PF a'100 blue

#### PRODUCT DESCRIPTION

<b>Type of the glove</b>	Examination, protective, powder free, non-sterile
<b>Material</b>	Nitrile
<b>Donning powder</b>	-
<b>Colour</b>	Blue
<b>Shape</b>	Ambidextrous
<b>Cuff</b>	Beaded
<b>External surface</b>	Textured on finger tips
<b>Packaging</b>	10 x 100 pcs

#### PRODUCT REFERENCES

<b>Size/ reference number</b>	XS	RD30019001
	S	RD30019002
	M	RD30019003
	L	RD30019004
	XL	RD30019005

#### PHYSICAL PROPERTIES

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

#### MANUFACTURING AND SAFETY STANDARDS

**AQL (Pin-Holes)** Manufacturing final release; GL-I AQL ≤ 1,5 in accordance with test result according to 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 374-1 excluding point 5.3.2
EN ISO 14971	EN 374-2
EN 455-1, EN 455-2, EN 455-3, EN 455-4	EN 374-3
EN 980	EN 420
EN 1041	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;

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