

# Technical Data Sheet



## nitrylex® black

### PRODUCT DESCRIPTION

<b>Type of the glove</b>	Non-sterile, powder free, examination and protective glove for single use
<b>Material</b>	Nitrile
<b>Donning powder</b>	-
<b>Colour</b>	Black
<b>Shape</b>	Ambidextrous, gloves fitting either hand
<b>Cuff</b>	Beaded
<b>External surface</b>	Microtextured + fingertip textured + polymerized
<b>Internal surface</b>	Polymerized + chlorinated
<b>Packaging</b>	10 x 100 pcs

### PRODUCT REFERENCES

<b>SIZE / REFERENCE NUMBER</b>	XS RD30104001
	S RD30104002
	M RD30104003
	L RD30104004
	XL RD30104005

### PHYSICAL PROPERTIES

Dimensions	Size	XS	S	M	L	XL
		(5-6)	(6-7)	(7-8)	(8-9)	(9-10)
<b>Length [mm]</b>		240	240	240	240	240
<b>Minimum</b>						
<b>Width [mm]</b>		≤80	80 ±10	95 ±10	110 ±10	≥110
<b>Thickness (single wall) [mm]</b>						
<b>Minimum</b>	Middle finger			0,09		
	Palm			0,06		
	Cuff			0,05		
<b>Elongation at break [%]</b>						
<b>Minimum</b>	Before ageing			500		
	After ageing			400		
<b>Force at break [N]</b>						
<b>Minimum</b>	Before ageing			6,0		
	After ageing			6,0		

### MANUFACTURING AND SAFETY STANDARDS

<b>AQL</b>	Manufacturing final release: G-I inspection level AQL 1.0 in accordance with ISO 2859-1	
<b>Protein content</b>	N/A	
<b>CE classification</b>	Class I – Medical Device (Regulation (EU) 2017/745)	Category III – Personal Protective Equipment (Regulation (EU) 2016/425)
<b>Compliances</b>	EN 455-1, EN 455-2, EN 455-3, EN 455-4 EN ISO 15223-1 EN 1041 EN ISO 13485	EN ISO 374-1 (Type B), EN 374-2, EN 374-4, EN ISO 374-5 EN 16523-1 EN 420
<b>Viral test</b>	Test in accordance with ISO 16604	
<b>Cytostatics permeation</b>	Test in accordance with ASTM D6978	
<b>Chemical substances permeation</b>	Test in accordance with EN 16523-1	
<b>Food contact</b>	Declaration of conformity for food contact in accordance with Regulation (EC) No 1935/2004 and with Commission Regulation (EU) No 10/2011 and Overall Migration Test in accordance with Commission Regulation (EU) No 10/2011	
<b>Shelf life</b>	3 years	

### STORAGE

<b>Storage instruction</b>	Keep out of direct sunlight. Store in a cool, dry place in temperature 5-35° C. Keep away from sources of ozone and ignition.
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