

Technical Data Sheet



nitrylex® classic (blue)

PRODUCT DESCRIPTION

Type of the glove	Non-sterile, powder free, examination and protective glove for single use
Material	Nitrile
Donning powder	-
Colour	Blue
Shape	Ambidextrous, gloves fitting either hand
Cuff	Beaded
External surface	Microtextured + fingertip textured, polymerized
Internal surface	Polymerized + chlorinated
Packaging	10 x 100 pcs 10 x 200 pcs

Dimensions

Length [mm]
Minimum

Width [mm]

Thickness (single wall) [mm]
Minimum

Elongation at break [%]
Minimum

Force at break [N]
Minimum

Size	XS (5-6)	S (6-7)	M (7-8)	L (8-9)	XL (9-10)
Length [mm]	240	240	240	240	240
Width [mm]	≤80	80 ±10	95 ±10	110 ±10	≥110
Thickness (single wall) [mm]					
Middle finger			0,06		
Palm			0,05		
Cuff			0,04		
Elongation at break [%]			500	400	
Force at break [N]			6,0	6,0	

PRODUCT REFERENCES

SIZE / REFERENCE NUMBER	XS	RD30019001	XS	RD30096001
	S	RD30019002	S	RD30096002
	M	RD30019003	M	RD30096003
	L	RD30019004	L	RD30096004
	XL	RD30019005	XL	RD30096005

MANUFACTURING AND SAFETY STANDARDS

AQL	Manufacturing final release: G-I inspection level AQL 1.0 in accordance with ISO 2859-1	
Protein content	N/A	
CE classification	Class I – Medical Device (Council Directive 93/42/EEC)	Category III – Personal Protective Equipment (Regulation (EU) 2016/425)
Compliances	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
Viral test	Test in accordance with ASTM F1671 & ISO 16604	
Cytostatics permeation	Test in accordance with ASTM D6978	
Chemical substances permeation	Test in accordance with EN 16523-1	
Food contact	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	
Shelf life	3 years	

STORAGE

Storage instruction	Keep out of direct sunlight. Store in a cool, dry place in temperature 5-35° C. Keep away from sources of ozone and ignition.	Prepared by: Wojciech Hercka – Product Documentation Manager Approved by: Katarzyna Nowakowska – Senior Product Manager
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