## **Technical Data Sheet**



## vinylex® powder-free

PRODUCT DESCRIPTION		PHYSICAL PROPERTIES						
Type of the glove	Non-sterile, powder free, examination and	Dimensions	Size	XS	S	М	L	XL
	protective glove for single use			(5-6)	(6-7)	(7-8)	(8-9)	(9-10)
Material	Polyvinyl chloride (vinyl)	Length [mm]		240	240	240	240	240
Donning powder	-	Minimum		240	240	240	240	240
Colour	Transparent	Width [mm]		≤80	80	95	110	≥110
Shape	Ambidextrous, gloves fitting either hand				±10	±10	±10	
Cuff	Beaded	Thickness				0.00		
External surface	Smooth	(single wall)	Middle finger			0,08		
Internal surface	Polyurethane coated	[mm]	Palm Cuff			0,07 0,05		
Packaging	10 x 100 pcs	Minimum	Cuii			0,03		
PRODUCT REFERENCES		Elongation at	Before ageing			300		
SIZE / REFERENCE	XS RD20018001	break [%]	After ageing			300		
NUMBER	S RD20018002	Minimum						
	M RD20018003	Force at	Before ageing			3,6		
	L RD20018004	break[N]	After ageing			3,6		
	XL RD20018005	Minimum						

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## **MANUFACTURING AND SAFETY STANDARDS**

AQL Manufacturing final release: G-I inspection level AQL 1.5 in accordance with ISO 2859-1

Protein content N/A

Class I – Medical Device (Regulation (EU) 2017/745) Category III – Personal Protective Equipment (Regulation (EU) 2016/425)

Compliances EN 455-1, EN 455-2, EN 455-3, EN 455-4 EN ISO 374-1 (Type C), EN 374-2, EN 374-4, EN ISO 374-5

EN ISO 15223-1 EN 1041 EN 420

EN ISO 13485

Viral test Passes test in accordance with ASTM F1671 & ISO 16604

Cytostatics N/A

permeation

permeation

Chemical substances Test in accordance with EN 16523-1 permeation

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.

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