

Technical Data Sheet



vinylex® PF

PRODUCT DESCRIPTION

Type of the glove	Examination, protective, powder free, non-sterile
Material	Polyvinyl chloride (vinyl)
Donning powder	-
Colour	Translucent
Shape	Ambidextrous
Cuff	Beaded
External surface	Smooth
Packaging	10 x 100 pcs

PRODUCT REFERENCES

Size/ reference number	XS	RD20018001
	S	RD20018002
	M	RD20018003
	L	RD20018004
	XL	RD20018005

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	240
Width [mm]		≤80	80± 10	95± 10	110± 10	≥110
Thickness (single wall) [mm]	Middle finger				0,08	
	Palm				0,07	
	Cuff				0,05	
Elongation at break [%]	Before ageing				300	
	After ageing				300	
Force at break [N]	Before ageing				3,6	
	After ageing				3,6	
	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 I, for minimal risk – Personal Protective Equipment (Council Directive 89/686/EEC)	
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 420
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.
----------------------------	---

Issue date: 21.06.2010

Update: 23.03.2015

Prepared by: Justyna Wiśniowska-Woźny – Technical Documentation Specialist

Approved by: Kinga Przygoda – Product Manager

Registered Office

ul. H. Modrzejewskiej 30
31-327 Kraków, Poland
ph./fax: +48 (12) 66 55 400
fax: +48 (12) 66 55 415
medical@mercatormedical.eu

Logistics Center

Stary Brześć 25E
87-880 Brześć Kujawski, Poland
ph./fax: +48 (54) 252 10 20
fax: +48 (12) 252 10 21
kujawy@mercatormedical.eu

VAT NO.: PL 677 10 36 424

REGON: 350967107

Registered in Poland: KRS 36244

Sąd Rejonowy dla Krakowa-Śródmieścia

XI Wydział Gospodarczy KRS

Paid-up capital: 8 643 400 PLN

ISO certificates (DNV CERTIFIED):

ISO 9001:2008;

no. 93133-2011-AQ-POL-FINAS

ISO 13485:2003;

no. 93134-2011-AQ-POL-FINAS

www.mercatormedical.eu

