MERCATOR MEDICAL

Technical Data Sheet



nitrylex® classic (blue)

PRODUCT DESCRIPTION					PHYSICAL PROPERTIES						
Type of the glove	Non-sterile, powder free, examination and			Dimensions	Size	XS	S	M	L	XL	
	prote	ective glove for si	ngle	use			(5-6)	(6-7)	(7-8)	(8-9)	(9-10)
Material	Nitrile				Length [mm]		240	240	240	240	240
Donning powder					Minimum		240	240	240	240	240
Colour	Blue				Width [mm]		≤80	80	95	110	≥110
Shape	Ambidextrous, gloves fitting either hand							±10	±10	±10	
Cuff	Beaded				Thickness						
External surface	Micro+ fingertip textured, polymerized				(single wall)	Middle finger			0,06		
Internal surface	Polymerized + chlorinated				[mm]	Palm Cuff			0,05 0,04		
Packaging	1	10 x 100 pcs		10 x 200 pcs	Minimum	Cuii			0,04		
PRODUCT REFERENCES					Elongation at	Before ageing			500		
SIZE / REFERENCE	XS	RD30019001	XS	RD30096001	break [%]	After ageing			400		
NUMBER	S	RD30019002	S	RD30096002	Minimum						
	М	RD30019003	M	RD30096003	Force at	Before ageing			6,0		
	L	RD30019004	L	RD30096004	break[N]	After ageing			6,0		
	XL	RD30019005	XL	RD30096005	Minimum						
MANUFACTURING AND SAFETY STANDARDS											

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Chemical substances

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 (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 B), EN 374-2, EN 374-4, EN ISO 374-5				

EN ISO 15223-1 EN 16523-1 EN 1041 EN 420 EN ISO 13485

Viral test Test in accordance with ASTM F1671 & ISO 16604

Test in accordance with ASTM D6978 Cytostatics permeation

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 **STORAGE**

Test in accordance with EN 16523-1

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

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