MERCATOR MEDICAL

Technical Data Sheet

nitrylex® classic (white)

PRODUCT DESCRIPTION

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

PRODUCT REFERENCES

SIZE / REFERENCE NUMBER				
XS	RD30143001	XS	RD30097001
S	RD30143002	S	RD30097002
M	RD30143003	M	RD30097003
L	RD30143004	L	RD30097004
XL	RD30143005	XL	RD30097005

PHYSICAL PROPERTIES

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

MANUFACTURING AND SAFETY STANDARDS

AQL	Manufacturing final release: G-I inspection level AQL 1.0 in accordance with ISO 2859-1	
Powder content	< 2 mg/glove	
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 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.