MERCATORMEDICAL

Technical Data Sheet

nitrylex® one by one

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	Micro+ fingertip textured, polymerized
Internal surface	Polymerized + chlorinated
Packaging	10 x 200 pcs

PRODUCT REFERENCES

SIZE / REFERENCE NUMBER		
XS	RD30124001
S	RD30124002
M	RD30124003
L	RD30124004
XL	RD30124005

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 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 and 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.