MERCATOR MEDICAL

Technical Data Sheet

santex® powdered

PRODUCT DESCRIPTION

Type of the glove	Non-sterile, powdered, examination and protective glove for single use
Material	Natural rubber latex
Donning powder	Modified corn starch (USP)
Colour	Creamy
Shape	Ambidextrous, gloves fitting either hand
Cuff	Beaded
External surface	Smooth
Internal surface	-
Packaging	10 x 100 pcs

PRODUCT REFERENCES

SIZE / REFERENCE NUMBER		
XS	RD11010001
S	RD11010002
M	RD11010003
L	RD11010004
XL	RD11010005

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	0,08
	Palm	0,08
	Cuff	0,075

Elongation at break [%] Minimum		
	Before ageing	700
	After ageing	500

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
Protein content	<150 µg/g glove (Modified Lowry's – EN 455-3)
CE classification	Class I – Medical Device (Council Directive 93/42/EEC) — 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 374-1 (excluding point 5.3.2.), EN 374-2, EN 374-3 / EN 420 / EN 388
Viral test	Passes test in accordance with ASTM F 1671
Cytostatics permeation	N/A
Chemical substances permeation	Test in accordance with EN 374-3
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	5 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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