

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	Natural white
Shape	Ambidextrous, gloves fitting either hand
Cuff	Beaded
External surface	Textured at finger tip
Internal surface	Powdered
Packaging	10 x 100 pcs

PRODUCT REFERENCES

SIZE / REFERENCE NUMBER	XS	S	M	L	XL
	RD11257001_1573	RD11257002_1573	RD11257003_1573	RD11257004_1573	RD11257005_1573

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		
Elongation at break [%] Minimum	Before ageing			650		
	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 1.5 in accordance with ISO 2859-1	
Protein content	<150 µg/g glove (Modified Lowry's – EN 455-3)	
Powder content	<10 mg/dm ² (acc. to EN 455-3)	
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 C), 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	Passes test in accordance with ASTM F 1671 and ISO 16604	
Cytostatics permeation	N/A	
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	5 years	

STORAGE

Storage instruction	Keep out of direct sunlight. Store in a cool, dry place in temperature 10-30° C. Keep away from sources of ozone and ignition.
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