

# Technical Data Sheet



## santex® powdered

### PRODUCT DESCRIPTION

<b>Type of the glove</b>	Non-sterile, powdered, examination and protective glove for single use
<b>Material</b>	Natural rubber latex
<b>Donning powder</b>	Modified corn starch (USP)
<b>Colour</b>	Natural white
<b>Shape</b>	Ambidextrous, gloves fitting either hand
<b>Cuff</b>	Beaded
<b>External surface</b>	Textured at finger tip
<b>Internal surface</b>	Powdered
<b>Packaging</b>	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)
<b>Length [mm]</b> Minimum		240	240	240	240	240
<b>Width [mm]</b>		≤80	80 ±10	95 ±10	110 ±10	≥110
<b>Thickness (single wall) [mm]</b> Minimum	Middle finger			0,08		
	Palm			0,08		
<b>Elongation at break [%]</b> Minimum	Before ageing			650		
	After ageing			500		
<b>Force at break [N]</b> Minimum	Before ageing			6,0		
	After ageing			6,0		

### MANUFACTURING AND SAFETY STANDARDS

<b>AQL</b>	Manufacturing final release: G-I inspection level AQL 1.5 in accordance with ISO 2859-1	
<b>Protein content</b>	<150 µg/g glove (Modified Lowry's – EN 455-3)	
<b>Powder content</b>	<10 mg/dm <sup>2</sup> (acc. to EN 455-3)	
<b>CE classification</b>	Class I – Medical Device (Regulation (EU) 2017/745)	Category III – Personal Protective Equipment (Regulation (EU) 2016/425)
<b>Compliances</b>	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	
<b>Viral test</b>	Passes test in accordance with ASTM F 1671 and ISO 16604	
<b>Cytostatics permeation</b>	N/A	
<b>Chemical substances permeation</b>	Test in accordance with EN 16523-1	
<b>Food contact</b>	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	
<b>Shelf life</b>	5 years	

### STORAGE

<b>Storage instruction</b>	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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