

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	Powdered (corn starch)
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]		240	240	240	240	240
Minimum						
Width [mm]		≤80	80	95	110	≥110
			±10	±10	±10	
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 (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 374-1 (Type C), EN 374-2, EN 374-4, EN ISO 374-5 EN 16523-1 EN 420
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 5-35° C. Keep away from sources of ozone and ignition.	