

### santex powdered



PRODUCT DESCRIPTION		PHYSICAL PROPERTIES						
<b>Manufacturer</b>	MERCATOR MEDICAL S.A. Ul. H. Modrzejewskiej 30 31-327 Kraków, Poland	<b>Size</b>	XS	S	M	L	XL	
<b>Type of glove</b>	non-sterile, powdered, examination and protective glove for single use	<b>Length [mm]</b>	Spec. [min]	240	240	240	240	
<b>Intended use</b>	gloves intended for use in medical field to protect patient and user from cross-contamination, intended to be used on one individual during a single procedure.	<b>Width [mm]</b>	Spec.	≤80	80 ±10	95 ±10	110 ±10	≥110
<b>Material</b>	natural rubber latex	<b>Force at break [N]</b>	Before ageing Spec. [min.]	6,0				
<b>Donning powder</b>	modified corn starch (USP)		After ageing Spec. [min.]	6,0				
<b>Colour</b>	white	<b>Powder content [mg/glove]</b>	Spec.	Not applicable, powdered gloves				
<b>Shape</b>	ambidextrous, gloves fitting either hand							
<b>Cuff</b>	beaded							
<b>External surface</b>	fingertip textured							
<b>Internal surface</b>	powdered							
MANUFACTURING AND SAFETY STANDARDS								
<b>AQL</b>	Manufacturing final release: G-I inspection level AQL 1.0 in accordance with ISO 2859-1.							
<b>Latex protein content</b>	<150 µg/g glove (Modified Lowry's – EN 455-3)							
<b>Classification</b>	<b>Medical Device: CE</b> Class I, Rule 5 (Regulation (EU) 2017/745)			<b>Personal Protective Equipment: CE 2777</b> Category III (Regulation (EU) 2016/425)				
<b>Product compliances</b>	EN 455-1, EN 455-2, EN 455-3, EN 455-4, EN ISO 15223-1, EN ISO 20417			EN ISO 374-1, EN ISO 374-2, EN ISO 374-4, EN ISO 374-5, EN 16523-1, EN ISO 21420				
<b>Quality compliances</b>	EN ISO 13485, ISO 9001							
<b>Viral test permeation</b>	Test in accordance with EN ISO 374-5 (ISO 16604) and ASTM F1671.							
<b>Bacteria and fungi permeation</b>	Test in accordance with EN ISO 374-5 (EN ISO 374-2).							
<b>Chemotherapy drugs permeation test</b>	Not applicable.							
<b>Chemical substances permeation test</b>	Test in accordance with EN 16523-1.							
<b>Biocompatibility / biological evaluation</b>	Test in accordance with EN ISO 10993-5. No cytotoxic evidence observed. Test in accordance with EN ISO 10993-10. No skin irritation and sensitization evidence observed.							
<b>REACH</b>	The product does not contain substances listed in candidate list according to Regulation (EC) 1907/2006.							
<b>Food contact</b>	Gloves intended for food contact based on Regulation (EU) No 10/2011, European Regulation (EC) No 1935/2004 and with Regulation (EC) No 2023/2006 on Good Manufacturing Practice. Gloves are suitable for handling of food and have been tested for Overall Migration Test acc. EN 1186.							
STORAGE AND DISPOSAL								
<b>Long-term storage instructions</b>	It is recommended to store the gloves in dry place, in the temperature of 5-35°C and to protect them against direct sunlight. Keep the gloves in a distance of not less than 1m from heating devices, sources of fire and ozone. Do not keep in direct vicinity of solvents, oils, fuels and lubricants.							
<b>Transport instructions</b>	Transport in conditions ensuring an appropriate hygienic standard, protecting the product against dirt. The product is not thermolabile - changing conditions regarding temperature or humidity in the short-term transport period do not affect the usability of the product or its properties or safety of use in any way. The product does not require transport in controlled conditions in terms of temperature and humidity (confirmed on the basis of accelerated aging tests and risk analysis).							
<b>Shelf life</b>	5 years from the manufacturing date							
<b>Product disposal</b>	The product must be disposed of in accordance with local regulations.							
<b>Packaging disposal</b>	Packaging made of homogeneous material, does not contain foil elements, does not contain different types of materials, does not require separation into fractions. The packaging is 100% recyclable in accordance with local regulations.							
PRODUCT REFERENCES								
<b>Transport carton</b>	<b>Size / REF number</b>							
	<b>XS</b>	<b>S</b>	<b>M</b>	<b>L</b>	<b>XL</b>			
<b>10 x 100 pcs</b>	RD11257001	RD11257002	RD11257003	RD11257004	RD11257005			