

vinylex powder-free



PRODUCT DESCRIPTION		PHYSICAL PROPERTIES						
Manufacturer	MERCATOR MEDICAL S.A. Ul. H. Modrzejewskiej 30 31-327 Kraków, Poland	Size		XS	S	M	L	XL
		Length [mm]	Spec. [min]	240	240	240	240	240
Type of glove	non-sterile, powder-free, examination and protective glove for single use	Width [mm]	Spec.	≤80	80 ±10	95 ±10	110 ±10	≥110
Intended use	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.	Force at break [N]	Before ageing Spec. [min.]	3,6				
			After ageing Spec. [min.]	3,6				
Material	polyvinyl chloride (vinyl)	Powder content [mg/glove]	Spec.	<2				
Donning powder	none							
Colour	transparent							
Shape	ambidextrous, gloves fitting either hand							
Cuff	beaded							
External surface	smooth							
Internal surface	polymerized (polyurethane coated)							
MANUFACTURING AND SAFETY STANDARDS								
AQL	Manufacturing final release: G-I inspection level AQL 1.5 in accordance with ISO 2859-1.							
Latex protein content	Not applicable. Gloves do not contain natural rubber latex.							
Classification	Medical Device: CE Class I, Rule 5 (Regulation (EU) 2017/745)		Personal Protective Equipment: CE 2777 Category III (Regulation (EU) 2016/425)					
Product compliances	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					
Quality compliances	EN ISO 13485, ISO 9001							
Viral test permeation	Test in accordance with EN ISO 374-5 (ISO 16604) and ASTM F1671.							
Bacteria and fungi permeation	Test in accordance with EN ISO 374-5 (EN ISO 374-2).							
Chemotherapy drugs permeation test	Not applicable.							
Chemical substances permeation test	Test in accordance with EN 16523-1.							
Biocompatibility / biological evaluation	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.							
REACH	The product does not contain substances listed in candidate list according to Regulation (EC) 1907/2006.							
Food contact	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								
Long-term storage instructions	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.							
Transport instructions	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).							
Shelf life	5 years from the manufacturing date							
Product disposal	The product must be disposed of in accordance with local regulations.							
Packaging disposal	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								
Transport carton	Size / REF number							
	XS	S	M	L		XL		
10 x 100 pcs	RD20018001	RD20018002	RD20018003	RD20018004		RD20018005		