

comfort® powder-free



PRODUCT DESCRIPTION		PHYSICAL PROPERTIES						
Manufacturer	MERCATOR MEDICAL S.A. Ul. H. Modrzejewskiej 30 31-327 Kraków	Size	XS (5-6)	S (6-7)	M (7-8)	L (8-9)	XL (9-10)	
Type of the glove	Non-sterile, powder-free, examination and protective glove for single use	Length [mm]	Spec. [min]	240	240	240	240	
Intended use	Gloves intended for use in the medical field to protect patient and user from cross-contamination, intended to be used on one individual during a single procedure.	Width [mm]	Spec.	≤80	80 ±10	95 ±10	110 ±10	≥110
Material	Natural rubber latex	Thickness (single wall) [mm]	Middle finger	Spec. [min]	0,08			
Donning powder	None		Palm	Spec. [min]	0,08			
Colour	Light yellow		Cuff	Spec. [min]	0,05			
Shape	Ambidextrous, gloves fitting either hand	Elongation at break [%]	Before ageing	Spec. [min]	650			
Cuff	Beaded		After ageing	Spec. [min]	500			
External surface	Fingertip textured	Force at break [N]	Before ageing	Spec. [min]	6,0			
Internal surface	Chlorinated		After ageing	Spec. [min]	6,0			
Packaging	10 x 100 pcs	Powder content [mg/glove]	Spec.	<2				
		Latex protein content [µg/g]	Spec.	<50				
PRODUCT REFERENCES								
Size / reference number	XS	RD10005001						
	S	RD10005002						
	M	RD10005003						
	L	RD10005004						
	XL	RD10005005						
MANUFACTURING AND SAFETY STANDARDS								
AQL	Manufacturing final release: G-I inspection level AQL 1.5 in accordance with ISO 2859-1							
Latex protein content	<50 µg/g glove (Modified Lowry's – EN 455-3)							
Residual powder content	<2 mg/glove (according to EN 455-3)							
Classification	Medical Device: CE class I (Regulation (UE) 2017/745)			Personal Protective Equipment: CE 2777 Category III (Regulation (UE) 2016/425) Type B (EN ISO 374-1)				
Product compliances	EN 455-1, EN 455-2, EN 455-3, EN 455-4, EN ISO 15223-1, EN 1041			EN ISO 374-1, EN ISO 374-2, EN 374-4, EN ISO 374-5, EN 16523-1, EN 420				
Quality compliances	EN ISO 13485, ISO 9001							
Viral test permeation	Test in accordance with ASTM F1671 and EN ISO 374-5 (ISO 16604)							
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.							
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 any type of food, except for acidic foods, and have been tested for Overall Migration Test acc. EN 1186.							
STORAGE AND DISPOSAL								
Storage instruction	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.							
Shelf life	3 or 5 years depends on LOT number (check the packaging)							
Disposal	The product must be disposed of in accordance with local regulations.							