

dermagel® coated



PRODUCT DESCRIPTION	
Manufacturer	MERCATOR MEDICAL S.A. Ul. H. Modrzejewskiej 30 31-327 Kraków
Type of the glove / Intended use	Non-sterile, powder-free, examination and protective glove for single use
Material	Natural rubber latex
Donning powder	None
Colour	Creamy
Shape	Ambidextrous, gloves fitting either hand
Cuff	Beaded
External surface	Textured
Internal surface	Polymer coated
Packaging	10 x 100 pcs

PRODUCT REFERENCES		
Size / reference number	XS	RD10006001
	S	RD10006002
	M	RD10006003
	L	RD10006004
	XL	RD10006005

PHYSICAL PROPERTIES							
Size			XS (5-6)	S (6-7)	M (7-8)	L (8-9)	XL (9-10)
Length [mm]	Spec. [min]		240	240	240	240	240
Width [mm]	Spec.		≤80	80 ±10	95 ±10	110 ±10	≥110
Thickness (single wall) [mm]	Middle finger	Spec. [min]	0,08				
	Palm	Spec. [min]	0,08				
	Cuff	Spec. [min]	0,075				
Elongation at break [%]	Before ageing	Spec. [min]	700				
	After ageing	Spec. [min]	500				
Force at break [N]	Before ageing	Spec. [min]	6,0				
	After ageing	Spec. [min]	6,0				
Powder content [mg/glove]	Spec.		<2				
Latex protein content [µg/g]	Spec.		<100				

MANUFACTURING AND SAFETY STANDARDS	
AQL	Manufacturing final release: G-I inspection level AQL 1.0 in accordance with ISO 2859-1
Latex protein content	<100 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	Used gloves should be treated as a contaminated material, therefore local regulations regarding the disposal of such materials should be applied.