MERCATOR

TECHNICAL DATA SHEET

dermagel coated



PRODUCT DESCRIPTION

Manufacturer	MERCATOR MEDICAL S.A. Ul. H. Modrzejewskiej 30 31-327 Kraków, Poland
Type of glove	non-sterile, powder-free, examination and protective glove for single use
Intended use	gloves intended for use in medical field to protect patient and user from cross-contamination, preventing perioperative infections during medical procedures (e.g. intravenous, intramuscular, intraarterial injections, dressing changes, wound revision, removal of surgical sutures), conducting medical examinations and medical treatment procedures, conducting diagnostic and therapeutic procedures, for handling medical contaminated material, intended to be used on one individual during a single procedure
Material	natural rubber latex
Donning powder	none
Colour	creamy
Shape	ambidextrous, gloves fitting either hand
Cuff	beaded
External surface	textured
Internal surface	polymer coated

PHYSICAL PROPERTIES

Size		XS	S	M	L	XL
Length [mm]	Spec. [min]	240	240	240	240	240
Width [mm]	Spec.	≤80	80 ±10	95 ±10	110 ±10	≥110
Force at break [N]	Before ageing Spec. [min.]	6,0				
	After ageing Spec. [min.]	6,0				
Powder content [mg/glove]	Spec.	<2				

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)	
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).	
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 5-40°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	RD10006001	RD10006002	RD10006003	RD10006004	RD10006005

* depends on LOT number (check the packaging)