MERCATOR

Technical Data Sheet

nitrylex® classic

PRODUCT DESCRIPTION

Manufacturer	MERCATOR MEDICAL S.A. Ul. H. Modrzejewskiej 30 31-327 Kraków	
Type of the glove	Non-sterile, powder-free, examination and protective glove for single use	
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.	
Material	Nitrile	
Donning powder	None	
Colour	White	
Shape	Ambidextrous, gloves fitting either hand	
Cuff	Beaded	
External surface	Microtextured + fingertip textured	
Internal surface	Chlorinated	
Packaging	10 x 100 pcs	10 x 200 pcs

PRODUCT REFERENCES

Size / reference number	XS	RD30143001	RD30097001
	S	RD30143002	RD30097002
	M	RD30143003	RD30097003
	L	RD30143004	RD30097004
	XL	RD30143005	RD30097005

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]	0,06				
	Palm	Spec. [min]	0,05				
	Cuff	Spec. [min]	0,04				
Elongation at break [%]	Before ageing Spec. [min]		500				
	After ageing Spec. [min]		400				
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.		Not applicable				

MANUFACTURING AND SAFETY STANDARDS

AQL	Manufacturing final release: G-I inspection level AQL 1.0 in accordance with ISO 2859-1	
Latex protein content	Not applicable. Gloves do not contain natural rubber latex.	
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 ISO 374-4 / EN 374-4, EN ISO 374-5, EN 16523-1, EN ISO 21420 / 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	Test in accordance with ASTM D6978.	
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 and have been tested for Overall Migration Test acc. EN 1186.	

STORAGE AND DISPOSAL

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.
Shelf life	3 or 5 years depend on LOT number (check the packaging)
Disposal	The product must be disposed of in accordance with local regulations.