

nitrylex® black



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 / Intended use	Non-sterile, powder-free, examination and protective glove for single use	Length [mm]	Spec. [min]		240	240	240	240	240
Material	Nitrile	Width [mm]	Spec.		≤80	80 ±10	95 ±10	110 ±10	≥110
Donning powder	None	Thickness (single wall) [mm]	Middle finger	Spec. [min]	0,09				
Colour	Black		Palm	Spec. [min]	0,06				
Shape	Ambidextrous, gloves fitting either hand		Cuff	Spec. [min]	0,05				
Cuff	Beaded	Elongation at break [%]	Before ageing	Spec. [min]	500				
External surface	Microtextured + fingertip textured		After ageing	Spec. [min]	400				
Internal surface	Chlorinated	Force at break [N]	Before ageing	Spec. [min]	6,0				
Packaging	10 x 100 pcs		After ageing	Spec. [min]	6,0				
PRODUCT REFERENCES		Powder content [mg/glove]	Spec.		<2				
		Latex protein content [µg/g]	Spec.		Not applicable				
Size / reference number	XS	RD30104001							
	S	RD30104002							
	M	RD30104003							
	L	RD30104004							
	XL	RD30104005							
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 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 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 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.								