MERCATOR MEDICAL

Technical Data Sheet



nitrylex[®] basic

	-							
PRODUCT DESCRIPTION		PHYSICAL PROPE						
Type of the glove	Non-sterile, powder free, examination and	Dimensions	Size	XS	S	Μ	L	XL
	protective glove for single use			(5-6)	(6-7)	(7-8)	(8-9)	(9-10)
Material	Nitrile	Length [mm]		240	240	240	240	240
Donning powder	-	Minimum		210		210	210	210
Colour	Blue (navy blue)	Width [mm]		≤80	80	95	110	≥110
Shape	Ambidextrous, gloves fitting either hand				±10	±10	±10	
Cuff	Beaded	Thickness	National Community			0.05		
External surface	Fingertips textured	(single wall) [mm]	Middle finger Palm			0,05 0,05		
Internal surface	Polymerized + chlorinated		Cuff			0,03		
Packaging	10 x 100 pcs 10 x 200 pcs	Minimum	cuit			0,01		
PRODUCT REFERENCES		Elongation at	Before ageing			500		
SIZE / REFERENCE	XS RD30105001 XS RD30084001	break [%]	After ageing			400		
NUMBER	S RD30105002 S RD30084002	Minimum						
	M RD30105003 M RD30084003	Force at	Before ageing			6,0		
	L RD30105004 L RD30084004	break[N]	After ageing			6,0		
	XL RD30105005 XL RD30084005	Minimum						
MANUFACTURING AND SAFETY STANDARDS								
AQL	Manufacturing final release: G-I inspection level AQL 1.5 in accordance with ISO 2859-1							
Protein content	N/A							
CE classification	Class I – Medical Device (Council Directive 93)	Category I, for minimal risk – Personal Protective Equipment						
			(Regulation (EU) 2016/425)					
Compliances	EN 455-1, EN 455-2, EN 455-3, EN 455-4	EN 420						
	EN ISO 15223-1							
	EN 1041 EN ISO 13485							
Viral test	N/A							
Vital test								
Cytostatics	N/A							
permeation								
Chemical substances	NI / A							
permeation	N/A							
Permeation								

Declaration of conformity for food contact in accordance with Regulation (EC) No 1935/2004 and with Commission Regulation (EU) No 10/2011 and Overall Migration Test in accordance with Commission Regulation (EU) No 10/2011 3 years

Shelf life STORAGE

Food contact

Storage instruction

Keep out of direct sunlight. Store in a cool, dry place in temperature 5-35° C. Keep away from sources of ozone and ignition.Issue date: 30.05.2017Prepared by: Wojciech Hercka – Product Documentation ManagerUpdate: 02.08.2019Approved by: Katarzyna Nowakowska – Product Manager