MERCATOR MEDICAL

Technical Data Sheet



nitrylex[®] basic

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PRODUCT DESCRIPTION		PHYSICAL PROPE	RTIES					
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		240	240	240	240	240
Colour	Blue (navy blue)	Width [mm]		≤80	80	95	110	≥110
Shape	Ambidextrous, gloves fitting either hand				±10	±10	±10	
Cuff	Beaded	Thickness						
External surface	Fingertips textured	(single wall)	Middle finger			0,05		
Internal surface	Polymerized	[mm]	Palm			0,05		
Packaging	10 x 100 pcs 10 x 200 pcs	Minimum	Cuff			0,04		
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	0 0					
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	Cate	gory I, for minimal	risk – Pers	onal Prote	ctive Faui	oment	
	(Regulation (EU) 2017/745)	(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							
Minal to at	EN ISO 13485							
Viral test	N/A							
Cytostatics	N/A							
permeation								
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Chemical substances	N/A							
permeation				/				()
Food contact	Declaration of conformity for food contact in a		• • •	-		ommissior	n Regulatio	on (EU)
	No 10/2011 and Overall Migration Test in accordance with Commission Regulation (EU) No 10/2011							
Shelf life	3 years							
STODACE								

STORAGE

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.