

Technical Data Sheet



dermagel® coated

PRODUCT DESCRIPTION

Type of the glove	Non-sterile, powder free, examination and protective glove for single use
Material	Natural rubber latex
Donning powder	-
Colour	Creamy
Shape	Ambidextrous, gloves fitting either hand
Cuff	Beaded
External surface	Textured
Internal surface	Polymer coated
Packaging	10 x 100 pcs

PRODUCT REFERENCES

SIZE / REFERENCE NUMBER	XS RD10006001
	S RD10006002
	M RD10006003
	L RD10006004
	XL RD10006005

PHYSICAL PROPERTIES

Dimensions	Size	XS (5-6)	S (6-7)	M (7-8)	L (8-9)	XL (9-10)
Length [mm]		240	240	240	240	240
Minimum						
Width [mm]		≤80	80	95	110	≥110
Thickness (single wall) [mm]			±10	±10	±10	
Minimum	Middle finger			0,08		
	Palm			0,08		
	Cuff			0,075		
Elongation at break [%]				700		
Minimum	Before ageing			500		
	After ageing					
Force at break [N]				6,0		
Minimum	Before ageing			6,0		
	After ageing					

MANUFACTURING AND SAFETY STANDARDS

AQL	Manufacturing final release: G-I inspection level AQL 1.0 in accordance with ISO 2859-1	
Protein content	<50 µg/g glove (Modified Lowry's – EN 455-3)	
CE classification	Class I – Medical Device (Regulation (EU) 2017/745)	Category III – Personal Protective Equipment (Regulation (EU) 2016/425)
Compliances	EN 455-1, EN 455-2, EN 455-3, EN 455-4 EN ISO 15223-1 EN 1041 EN ISO 13485	EN ISO 374-1 (Type B), EN 374-2, EN 374-4, EN ISO 374-5 EN 16523-1 EN 420
Viral test	Test in accordance with ASTM F1671 and ISO 16604	
Cytostatics permeation	N/A	
Chemical substances permeation	Test in accordance with EN 16523-1	
Food contact	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	
Shelf life	3 years	

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.
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