MERCATOR MEDICAL Protecting.

Technical Data Sheet



dermaGEL[®]

PRODUCT DESCRIPTION		PHYSICAL PROPERTIES						
Type of the glove	Examination, protective, powder free, non- sterile glove	Dimension	Size	XS (5-6)	S (6-7)	M (7-8)	L (8-9)	XL (9-10)
Material Donning powder	Natural rubber latex -	Length [mm] Minimum		240	240	240	240	240
Colour Shape Cuff	Creamy Ambidextrous Beaded	Width [mm]		≤80	80± 10	95± 10	110± 10	≥110
External surface Internal surface Packaging	Textured Non-latex polymer coating 10 x 100 pcs	Thickness (single wall) [mm] Minimum	Middle finger Palm Cuff			0	,08 ,08 075	
PRODUCT REFERENCE Size/ reference number	XS RD10006001 S RD10006002 M RD10006003 L RD10006004 XL RD10006005	Elongation at break [%] Force at break [N] Minimum	Before ageing After ageing Before ageing After ageing			5	00 00 5,0 5,0	

MANUEACTURING AND SAFETY STANDARDS

WANUFACTURING	AND SAFETY STANDARDS				
AQL (Pin-Holes)	Manufacturing final release; GL-I AQL \leq 1,5 in accordance with test result according the procedure ISO 2859				
Protein content	<50 μg/g glove (Modified Lowry's – EN 455-3)				
CE classification	Class I – Medical Device (Council Directive 93/42/EEC and Directive 2007/47/EC) Category I, for minimal risk – Personal Protective Equipment (Council Directive 89/686/EEC)				
Compliances	EN ISO 13485 EN ISO 14971 EN 455-1, EN 455-2, EN 455-3, EN 455-4 EN 980 EN 1041	EN 374-1 excluding point 5.3.2 EN 374-2 EN 420			
Viral test	Passes test in accordance with ASTM F 1671				
Chemical substances permeation	Test in accordance with EN 374-3				
Shelf life	5 years				
STORAGE					
Storage instruction	Keep out of direct sunlight. Store in a cool, dry place in temperature 5-30° C. Keep away from sources of ozone and ignition.				
	Issue date: 21.06.2010 Update: 23.03.2015	Prepared by: Justyna Wiśniowska-Woźny – Technical Documentation Specialist Approved by: Kinga Przygoda – Product Manager			

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VAT NO.: PL 677 10 36 424 **REGON:** 350967107 Registered in Poland: KRS 36244 Sąd Rejonowy dla Krakowa-Śródmieścia ISO 13485:2003; XI Wydział Gospodarczy KRS Paid-up capital: 8 643 400 PLN

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