

## Technical Data Sheet



### dermaGEL®

#### PRODUCT DESCRIPTION

<b>Type of the glove</b>	Powder free, sterile surgical glove
<b>Material</b>	Natural rubber latex
<b>Donning powder</b>	-
<b>Colour</b>	Creamy
<b>Shape</b>	Anatomic, hand specific
<b>Cuff</b>	Beaded
<b>External surface</b>	Textured
<b>Internal surface</b>	Non-latex polymer coating
<b>Packaging</b>	8 x 50 pairs

#### PRODUCT REFERENCES

<b>Size/ reference number</b>	6,0	RC10005060
	6,5	RC10005065
	7,0	RC10005070
	7,5	RC10005075
	8,0	RC10005080
	8,5	RC10005085
	9,0	RC10005090

#### PHYSICAL PROPERTIES

<b>Dimensions</b>	Size	6,0	6,5	7,0	7,5	8,0	8,5	9,0
<b>Length [mm]</b>		260	260	270	270	270	280	280
Minimum								
<b>Width [mm]</b>		77	83	89	95	102	108	114
		±5	±5	±5	±5	±6	±6	±6
<b>Thickness (single wall) [mm]</b>	Middle finger							0,21
	Palm							0,20
	Cuff							0,15
Minimum								
<b>Elongation at break [%]</b>	Before ageing							920
	After ageing							820
Minimum								
<b>Force at break [N]</b>	Before ageing							9,0
	After ageing							9,0
Minimum								

#### MANUFACTURING AND SAFETY STANDARDS

<b>AQL (Pin-Holes)</b>	Manufacturing final release; GL-I AQL 1.0 in accordance with test result according the procedure ISO 2859	
<b>Protein content</b>	<50 µg/g glove (modified Lowry's assay EN 455-3)	
<b>Sterilization</b>	Ethylene oxide (EO)	
<b>CE classification</b>	Class IIa – Medical Device (Council Directive 93/42/EEC and Directive 2007/47/EC) EC Certificate issue by Det Norske Veritas Notified Body 0434 Category III – Personal Protective Equipment (Council Directive 89/686/EEC) EC Type Examination Certificate issue by SGS Notified Body 0120	
<b>Compliances</b>	EN ISO 13485 EN 455-1, EN 455-2, EN 455-3, EN 455-4 EN ISO 11135-1 EN 556-1, EN 420	EN 374-1 (excluding point 5.3.2) EN 374-2 EN 374-3 EN 388
<b>Viral test</b>	Passes test in accordance with ASTM F 1671-07	
<b>Chemical substances permeation</b>	Test in accordance with EN 374-3	
<b>Shelf life</b>	3 years	

#### STORAGE

<b>Storage instruction</b>	Keep out of direct sunlight. Store in a cool, dry place in temperature 5-30° C. Keep away from sources of ozone and ignition.
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**ISO certificates (DNV CERTIFIED):**  
ISO 9001:2008;  
no. 93133-2011-AQ-POL-FINAS  
ISO 13485:2003;  
no. 93134-2011-AQ-POL-FINAS  
[www.mercatormedical.eu](http://www.mercatormedical.eu)

