

Technical Data Sheet



gynoglove®

PRODUCT DESCRIPTION

Type of the glove	Powder free, sterile surgical glove with longer cuff
Material	Natural rubber latex
Donning powder	-
Colour	Pale yellow
Shape	Anatomic, hand specific
Cuff	Beaded
External surface	Chlorinated, textured
Internal surface	Chlorinated
Packaging	4 x 25 pairs

PRODUCT REFERENCES

Size/ reference number	6,5	RC10007065
	7,5	RC10007075
	8,5	RC10007085

PHYSICAL PROPERTIES

Dimensions	Size	6,5	7,5	8,5
Length [mm]		480	480	480
Minimum				
Width [mm]		83±3	95±5	108±6
Thickness (single wall) [mm]	Middle finger			0,24
	Palm			0,23
	Cuff			0,15
Minimum				
Elongation at break [%]	Before ageing			900
	After ageing			840
Minimum				
Force at break [N] Minimum	Before ageing			9,0
	After ageing			9,0

MANUFACTURING AND SAFETY STANDARDS

AQL (Pin-Holes)	Manufacturing final release; GL-I AQL 1.0 in accordance with test result according the procedure ISO 2859	
Protein content	<50 µg/g glove (modified Lowry's EN 455-3)	
Sterilization	Gamma (R)	
CE classification	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 I for minimal risk – Personal Protective Equipment (Council Directive 89/686/EEC)	
Compliances	EN ISO 13485 EN 455-1, EN 455-2, EN 455-3, EN 455-4 EN 556-1 EN ISO 11137-1	EN 374-1 (excluding point 5.3.2) EN 374-2 EN 420
Viral test	Passes test in accordance with ASTM F 1671-07	
Shelf life	3 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.
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Prepared by: Justyna Wiśniowska-Woźny – Product Specialist
Approved by: Kinga Przygoda – Product Manager

Registered Office
ul. H. Modrzejewskiej 30
31-327 Kraków, Poland
ph./fax: +48 (12) 66 55 400
fax: +48 (12) 66 55 415
medical@mercatormedical.eu

Logistics Center
Stary Brześć 25E
87-880 Brześć Kujawski, Poland
ph./fax: +48 (54) 252 10 20
fax: +48 (12) 252 10 21
kujawy@mercatormedical.eu

VAT NO.: PL 677 10 36 424
REGON: 350967107
Registered in Poland: KRS 36244
Sąd Rejonowy dla Krakowa-Śródmieścia
XI Wydział Gospodarczy KRS
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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

