**MERCATOR** MEDICAL Protecting.

## **Technical Data Sheet**



# ambulance<sup>®</sup> PF

PRODUCT DESCRIPTION				PHYSICAL PROPERTIES					
Type of the glove	Examination, protective, powder free, non- sterile glove with longer cuff			Dimension	Size	S (6-7)	M (7-8)	L (8-9)	XL (9-10)
Material	Natural rubber latex			Length [mm]		295	295	295	295
Donning powder	-			Minimum					
Colour	Darkblue			Width [mm]		80±10	95±10	110±10	≥110
Shape	Ambidextrous			Thickness (single	Middle finger 0,33				
Cuff	Beaded			wall) [mm]	Palm 0,32				
External surface	Textured			Minimum	Cuff 0,20				
Packaging	10 x 50 pcs								
PRODUCT REFERENCES				Elongation at	Before ageing 650				
Size/ reference	S	RD10011002		break [%]	After ageing			500	
number	Μ	RD10011003							
	L	RD10011004		Force at break	Before agei	0		6,	
	XL	RD10011005		<b>[N]</b> Minimum	After ageing	B		6,	0

## MANUFACTURING AND SAFETY STANDARDS

MANUFACIURING	AND SAFETY STANDARDS					
AQL	Manufacturing final release; GL-I AQL ≤ 1,5 in accordance with test result according the procedure ISO 2859					
(Pin-Holes)						
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 III – Personal Protective Equipment (Council Directive 89/686/EEC) EC Type Examination Certificate issued by SATRA Notified Body 0321					
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 EN 374-2 EN 374-3 EN 420 EN 388				
Viral test	Passes test in accordance with ASTM F 1671					
Cytostatics permeation	Test in accordance with ASTM D 6978-05					
Chemical substances permeation	Test in accordance with EN 374-3					
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 ig					
	Issue date: 21.06.2010	Prenared by: Justyna Wiśniowska-Woźny – Technical Documentation Specialist				

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Prepared by: Justyna Wiśniowska-Woźny – Technical Documentation 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 ISO 13485:2003; XI Wydział Gospodarczy KRS Paid-up capital: 8 643 400 PLN

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