

Technical data sheet



ambulance® PF

Type of the glove

Material

Donning powder

AQL

Protein content

Colour

Shape

Cuff

External surface

Packaging

Powder free, non sterile examination glove, thicker and longer cuff latex

Manufacturing final release; GL-I AQL ≤ 1,5 in accordance with test result according the procedure ISO 2859

<50 µg/g glove (Modified Lowry's – EN 455-3)

darkblue

ambidextrous

beaded

textured

10 x 50 pcs

Dimension

Minimum values

Size		S (6-7)	M (7-8)	L (8-9)	XL (9-10)
Length	[mm]	295	295	295	295
Width	[mm]	80±10	95±10	110±10	≥110

Thickness (single wall)

Minimum values

Middle finger	[mm]	0,33
Palm	[mm]	0,32
Cuff	[mm]	0,20

Physical properties

Minimum values

	Before aging	After aging
Elongation at break [%]	650	500
Force at break [N]	9,0	6,0

CE classification

Compliances

Class I - Medical Device

Category I for minimal risk - PPE

EN 980, EN 1041, EN ISO 14971, EN ISO 13485, EN 455-1, EN 455-2, EN 455-3, EN 455-4

This product is in conformity with all provisions of the Council Directive 93/42/EEC concerning medical devices amended by the Directive 2007/47/EC which applied to it.

EN 374-1 excluding point 5.3.2, EN 374-2, EN 420

This product is in conformity with all provisions of Council Directive 89/686/EEC relating to personal protective equipment and is classified as the Personal Protective Equipment (PPE) of category I – for minimal risk.

Chemical substances permeation

Storage instruction

Shelf life

Test in accordance with EN 374 -3

Keep out of direct sunlight. Store in a cool, dry place in temperature 5-30°C. Keep away from sources of ozone and ignition.

3 years

Date: 2010.06.21 Update: 2014.01.02

Issue: 4

Issued by: Justyna Wiśniowska-Woźny – Technical Documentation Specialist

Approved by: Agnieszka de Mehlem – Product Manager

MERCATOR MEDICAL

Spółka Akcyjna

ul. Heleny Modrzejewskiej 30

31-327 Kraków

tel. +48 12 66 55 400, fax +48 12 66 55 415

-6-

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

Paid-up capital: 8 643 400 PLN

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

