**MERCATOR** MEDICAL Protecting.

## **Technical Data Sheet**



## nitrylex<sup>®</sup> PF txt

PRODUCT DESCRIPTION		PHYSICAL PROPERTIES						
Type of the glove	Examination, protective, powder free, non- sterile	Dimension	Size	XS (5-6)	S (6-7)	M (7-8)	L (8-9)	XL (9-10)
Material Donning powder	Nitrile -	<b>Length [mm]</b> Minimum		240	240	240	240	240
Colour Shape Cuff	Blue Ambidextrous Beaded	Width [mm]		≤80	80± 10	95± 10	110± 10	≥110
External surface Packaging	Textured 10 x 100 pcs	Thickness (single wall) [mm]	Middle finger Palm Cuff			0, 0, 0,	10	
PRODUCT REFERENC	XS RD30088001	Minimum	cun			0,	50	
number	S         RD30088001           S         RD30088002           M         RD30088003           L         RD30088004	Elongation at break [%]	Before ageing After ageing			50 40	)0 )0	
	XL RD30088005	Force at break [N] Minimum	Before ageing After ageing			6, 6,		

MANUFACTURING	AND SAFETY STANDARDS				
AQL	Manufacturing final release; GL-I AQL $\leq$ 1,5 in accordance with test result according the procedure ISO 2859				
(Pin-Holes)					
Protein content	Not applicable				
<b>CE</b> 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 issue by SATRA Notified Body 0321				
Compliances	EN ISO 13485	EN 374-1 excluding point 5.3.2			
	EN ISO 14971	EN 374-2			
	EN 455-1, EN 455-2, EN 455-3, EN 455-4	EN 374-3			
	EN 980	EN 420			
	EN 1041	EN 388			
Viral test	Passes test in accordance with ASTM F 1671				
Chemical	Test in accordance with EN 374-3				
substances					
permeation					
Shelf life	3 years				
STORAGE					
Storage	Keep out of direct sunlight. Store in a cool, dry place in temperature 5-30° C. Keep away from sources of ozone and ignition.				
instruction					
	Issue date: 31.03.2014	Prepared by: Justyna Wiśniowska-Woźny – Technical Documentation Specialist			

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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

Approved by: Kinga Przygoda – Product Manager

ISO certificates (DNV CERTIFIED): ISO 9001:2008; no. 93133-2011-AQ-POL-FINAS no. 93134-2011-AQ-POL-FINAS www.mercatormedical.eu

