

## Technical Data Sheet



### nitrylex® PF COLLAGEN

#### PRODUCT DESCRIPTION

<b>Type of the glove</b>	Examination, protective, powder free, non-sterile
<b>Material</b>	Nitrile
<b>Donning powder</b>	-
<b>Colour</b>	Pink
<b>Shape</b>	Ambidextrous
<b>Cuff</b>	Beaded
<b>External surface</b>	Textured on finger tips
<b>Internal surface</b>	Collagen and allantoin coated
<b>Packaging</b>	10 x 100 pcs

#### PRODUCT REFERENCES

<b>Size/ reference number</b>	XS	RD30095001
	S	RD30095002
	M	RD30095003
	L	RD30095004
	XL	RD30095005

#### PHYSICAL PROPERTIES

Dimension	Size	XS	S	M	L	XL
		(5-6)	(6-7)	(7-8)	(8-9)	(9-10)
<b>Length [mm]</b>		240	240	240	240	240
Minimum						
<b>Width [mm]</b>		≤80	80±10	95±10	110±10	≥110
<b>Thickness (single wall) [mm]</b>	Middle finger				0,08	
	Palm				0,06	
	Cuff				0,05	
<b>Elongation at break [%]</b>	Before ageing				500	
	After ageing				400	
<b>Force at break [N] Minimum</b>	Before ageing				6,0	
	After ageing				6,0	

#### MANUFACTURING AND SAFETY STANDARDS

<b>AQL (Pin-Holes)</b>	Manufacturing final release; GL-I AQL ≤ 1,5 in accordance with test result according the procedure ISO 2859	
<b>Protein content</b>	Not applicable	
<b>CE classification</b>	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	
<b>Compliances</b>	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 excluding point 5.3.2 EN 374-2 EN 374-3 EN 420 EN 388
<b>Viral test</b>	Passes test in accordance with ASTM F 1671	
<b>Cytostatics permeation</b>	Test in accordance with ASTM D 6978-05	
<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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Issue date: 02.01.2014  
Update: 23.03.2015

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**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](http://www.mercatormedical.eu)

