

Technical Data Sheet



comfort® PF

PRODUCT DESCRIPTION

Type of the glove	Examination, protective, powder free, non-sterile glove
Material	Natural rubber latex
Donning powder	-
Colour	Creamy
Shape	Ambidextrous
Cuff	Beaded
External surface	Textured
Packaging	10 x 100 pcs

PRODUCT REFERENCES

Size/ reference number	XS	RD10005001
	S	RD10005002
	M	RD10005003
	L	RD10005004
	XL	RD10005005

PHYSICAL PROPERTIES

Dimension	Size	XS (5-6)	S (6-7)	M (7-8)	L (8-9)	XL (9-10)
Length [mm] Minimum		240	240	240	240	240
Width [mm]		≤80	80± 10	95± 10	110± 10	≥110
Thickness (single wall) [mm] Minimum	Middle finger				0,10	
	Palm				0,08	
	Cuff				0,075	
Elongation at break [%]	Before ageing				700	
	After ageing				500	
Force at break [N] Minimum	Before ageing				6,0	
	After ageing				6,0	

MANUFACTURING AND SAFETY STANDARDS

AQL (Pin-Holes)	Manufacturing final release; GL-I AQL ≤ 1,5 in accordance with test result according the procedure ISO 2859	
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 Centexbel Notified Body 0493	
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 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 ignition.
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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
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