

Technical Data Sheet



comfort® PF

PRODUCT DESCRIPTION

Type of the glove	Powder free, sterile surgical glove
Material	Natural rubber latex
Donning powder	-
Colour	Pale yellow
Shape	Anatomic, hand specific
Cuff	Beaded
External surface	Chlorinated, textured
Internal surface	Chlorinated
Packaging	8 x 50 pairs

PRODUCT REFERENCES

Size/ reference number	6,0	RC10003060
	6,5	RC10003065
	7,0	RC10003070
	7,5	RC10003075
	8,0	RC10003080
	8,5	RC10003085
	9,0	RC10003090

PHYSICAL PROPERTIES

Dimensions	Size	6,0	6,5	7,0	7,5	8,0	8,5	9,0
Length [mm]		260	260	270	270	270	280	280
Minimum								
Width [mm]		77	83	89	95	102	108	114
±		±5	±5	±5	±5	±6	±6	±6
Thickness (single wall) [mm]	Middle finger							0,21
	Palm							0,19
	Cuff							0,14
Minimum								
Elongation at break [%]	Before ageing							900
	After ageing							860
Minimum								
Force at break [N]	Before ageing							9,0
	After ageing							9,0
Minimum								

MANUFACTURING AND SAFETY STANDARDS

AQL (Pin-Holes)	Manufacturing final release; GL-I AQL 1.0 in accordance with test result according the procedure ISO 2859	
Protein content	<50 µg/g glove (modified Lowry's assay EN 455-3)	
Sterilization	Ethylene oxide (EO)	
CE classification	Class IIa – Medical Device (Council Directive 93/42/EEC and Directive 2007/47/EC) EC Certificate issue by Det Norske Veritas 0434 Category III – Personal Protective Equipment (Council Directive 89/686/EEC) EC Type Examination Certificate issue by SGS Notified Body 0120	
Compliances	EN ISO 13485 EN 455-1, EN 455-2, EN 455-3, EN 455-4 EN ISO 11135-1 EN 556-1, EN 420	EN 374-1 (excluding point 5.3.2) EN 374-2 EN 374-3 EN 388
Viral test	Passes test in accordance with ASTM F 1671-07	
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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