

## Technical Data Sheet



### proHAND® PF NITRILE

#### PRODUCT DESCRIPTION

<b>Type of the glove</b>	Powder free, sterile examination glove
<b>Material</b>	Nitrile
<b>Donning powder</b>	-
<b>Colour</b>	Blue
<b>Shape</b>	Ambidextrous, gloves fitting either hand
<b>Cuff</b>	Beaded
<b>External surface</b>	Fingers textured
<b>Internal surface</b>	Chlorinated
<b>Packaging</b>	6 x 50 pairs

#### PRODUCT REFERENCES

<b>Size/ reference number</b>	S	RC30015002
	M	RC30015003
	L	RC30015004
	XL	RC30015005

#### PHYSICAL PROPERTIES

<b>Dimensions</b>	Size	S	M	L	XL
<b>Length [mm]</b> Minimum		240	240	240	240
<b>Width [mm]</b>		80 ±10	95 ±10	110 ±10	≥ 110
<b>Thickness (single wall) [mm]</b> Minimum	Middle finger				0,05
	Palm				0,05
<b>Elongation at break [%]</b> Minimum	Before ageing				650
	After ageing				500
<b>Force at break [N]</b> Minimum	Before ageing				6,0
	After ageing				6,0

#### MANUFACTURING AND SAFETY STANDARDS

<b>AQL (Pin-Holes)</b>	Manufacturing final release; GL-I AQL 1.0 in accordance with test result according the procedure ISO 2859	
<b>Protein content</b>	Not applicable	
<b>Sterilization</b>	Ethylene oxide (EO)	
<b>CE classification</b>	Class I sterile – Medical Device (Council Directive 93/42/EEC and Directive 2007/47/EC) EC Certificate issue by Det Norske Veritas Notified Body 0434 Category I, for minimal risk – Personal Protective Equipment (Council Directive 89/686/EEC)	
<b>Compliances</b>	EN ISO 13485 EN 455-1, EN 455-2, EN 455-3, EN 455-4 EN 556-1 EN ISO 11135-1	EN 374-1 (excluding point 5.3.2) EN 374-2 EN 420
<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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**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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