

## Synsation™ PF

Synthetic Powder-Free Non-Sterile Examination Glove

Issue date 13-11-2014

### PRODUCT DESCRIPTION

<b>Material</b>	Polyvinyl chloride (Vinyl)
<b>Colour</b>	Translucent
<b>Shape</b>	Ambidextrous
<b>Cuff</b>	Beaded
<b>External Surface</b>	Smooth
<b>Internal Surface</b>	-

### PHYSICAL PROPERTIES

<b>Thickness (single)</b> Typical average values (mm)	Finger	0,115
	Palm	0,100
	Cuff	0,075
<b>Minimum length (mm)</b>	240	
<b>Strength (average values)</b>	before ageing	after ageing
<b>Elongation at Break (%)</b>	390	370
<b>Force at break (N)</b>	4,8	5,3

### PACKAGING AND STORAGE

<b>Packaging</b>	10 x 100 pieces / 1000 pieces per case
<b>Shelf Life</b>	3 years
<b>Storage Instructions</b>	Keep out of direct sunlight. Store in a cool and dry place. Keep away from sources of ozone or ignition.

### PRODUCT REFERENCES

<b>Size / product code</b>	<b>x-small</b>	4001OXS	<b>small</b>	4001OS
	<b>medium</b>	4001OM	<b>large</b>	4001OL
	<b>x-large</b>	4001OX		

### KEY FEATURES AND ADVANTAGES

- Powder-free
- Smooth surface
- Translucent

### MANUFACTURING AND SAFETY STANDARDS

<b>AQL (pinholes)</b>	<ul style="list-style-type: none"> <li>• Waterleak tested</li> <li>• Conform European Norm EN 455-1: Inspection Level I AQL 1.5</li> </ul>
<b>Protein content</b>	Not applicable: contains no natural rubber latex
<b>Pyrogenicity</b>	Absent of pyrogens as per ISO 10993-11
<b>Primary skin irritation</b>	Not considered a primary irritant as per FHSA Regulation guidelines 16 CFR 1500
<b>Skin Sensitization</b>	No evidence of delayed dermal contact sensitisation as per ISO 10993-10
<b>Viral Penetration</b>	Passes ASTM F 1671 using Phi X 174
<b>Cytostatic Permeation</b>	ACPP tested under dynamic conditions
<b>Sterilization</b>	Not Applicable
<b>CE Mark</b>	Medical Device: Class I Personal Protective Equipment: Category III
<b>Product Standards Conformance</b>	EN 455 parts 1, 2, 3, 4 EN 374 parts 1, 2, 3 EN 420
<b>Manufacturing Standards</b>	ISO 13485 ISO 9001
<b>Registering Authority</b>	Centexbel (0493): PPE

### PICTOGRAMS



EN374 EN374

Please consult the Instruction for Use.

