

### ENCORE Non-Latex PI Hybrid in SMART Pack

Synthetic Polyisoprene and Neoprene Powder-Free Sterile Surgical Glove

Issue date 25-02-2020

#### PRODUCT DESCRIPTION

<b>Material</b>	Synthetic Polyisoprene and Neoprene
<b>Colour</b>	Cream
<b>Shape</b>	Anatomic
<b>Cuff</b>	SureFit™ technology: Beaded cuff with adhesive band
<b>External Surface</b>	Textured, Chlorinated & Siliconized
<b>Internal Surface</b>	Polyurethane coated & Siliconized

#### PHYSICAL PROPERTIES

<b>Thickness (single)</b>	Finger	0.215
	Typical average values (mm)	0.200
	Cuff	0.170
<b>Minimum length (mm)</b>	305	
<b>Strength (average values)</b>	before ageing	after ageing
<b>Elongation at Break (%)</b>	986	923
<b>Force at break (N)</b>	13.0	15.0

#### PACKAGING AND STORAGE

<b>Packaging</b>	4 x 50 pairs / 200 pairs 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>5.5</b>	340105055	<b>6</b>	340105060
	<b>6.5</b>	340105065	<b>7</b>	340105070
	<b>7.5</b>	340105075	<b>8</b>	340105080
	<b>8.5</b>	340105085	<b>9</b>	340105090

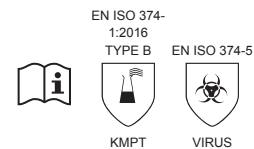
#### KEY FEATURES AND ADVANTAGES

- Anatomic curved former for less hand fatigue
- Free of Natural Rubber Latex for preventing type I allergies
- Unique formulation for excellent comfort, strength & durability

#### 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> <li>• Manufacturing Final Release: Inspection Level I AQL 0.65</li> <li>• In process control before packaging: Inspection Level I AQL 0.65</li> </ul>
<b>Protein content</b>	Not applicable: contains no natural rubber latex
<b>Pyrogenicity</b>	Absent of pyrogens as per ISO 10993-10
<b>Primary skin irritation</b>	Considered a negligible irritant as per ISO 10993-11
<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>	ASTM D6978 Breakthrough Times available
<b>Sterilization</b>	25 kGy Gamma irradiation
<b>CE Mark</b>	Personal Protective Equipment: Category III Medical Device: Class IIa
<b>Product Standards Conformance</b>	EN 455 parts 1, 2, 3, 4 EN 420 EN ISO 374 part 1 EN 374 part 2 EN 16523 part 1 EN 374 part 4 EN ISO 374 part 5
<b>Manufacturing Standards</b>	EN 556 ISO 11137-1 ISO 13485 ISO 14001 ISO 9001
<b>Registering Authority</b>	British Standards Institution (2797): MD Centexbel (0493): PPE

#### PICTOGRAMS



Please consult the Instruction for Use.

