

HPC Healthline UK Ltd declares that the PPE described hereafter:

Handsafe Powder Free Latex Examination Glove (GN32)

» is in conformity with the provisions of Council Directive 89/686/EEC and, where such is the case, with the national standard transposing harmonized standard:

BS EN 420:2003 + A1:2009	Protective gloves – general requirements and test methods
BS EN 374-1:2003	Protective gloves against chemicals and micro- organisms - terminology and performance requirements
BS EN 374-2:2003	Protective gloves against chemicals and micro- organisms - determination of resistance to penetration
BS EN 374-3:2003	Protective gloves against chemicals and micro- organisms - determination of resistance to permeation

- Is identical to the PPE which is the subject of EC certificate of conformity no. CE 585139 » issued by British Standards Institute Group (BSI Group), Kitemark Court, Davy Avenue, Knowhill, Milton Keynes, MK5 8PP, United Kingdom.
- Is subject to the procedure set out in Article 11 point A of Directive 89/686/EEC under » the supervision of the approved body British Standards Institute Group (BSI Group), Kitemark Court, Davy Avenue, Knowhill, Milton Keynes, MK5 8PP, United Kingdom, under CE 585148 article 11A.

Done:

1.6.1

Name:

Signature:

Scott Prichard

Position:

Director

Place of Issue: Morden, UK Date:

09 June 2015

File Ref:	HPC-DOC- 026 GN32 PPE	<b>Revision:</b>	2
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HPC Healthline UK Ltd, Colwood House, 158 Garth Road, Morden, Surrey, SM4 4LZ, United Kingdom

## **Declaration of Conformity**



Manufacturer:	HPC Healthline UK Limited, Colwood House, 158 Garth Road, Morden, Surrey, SM4 4LZ, UK.	
Product	GN32 Powder Free Latex Medical Examination Glove	
Brand Name:	Handsafe	
Classification:	Class I (According to Annex IX, Rule 5 of Council Directive 93/42/EEC, as amended by directive 2007/47/EC).	
Conformity Assessment Route:	ANNEX VII: Self declaration that the products of this declaration meet the provisions of Council Directive 93/42/EEC, as amended by directive 2007/47/EC.	
Harmonised Standards:	<ul> <li>Medical gloves for single use:</li> <li>BS EN 455-1 Freedom from Holes</li> <li>BS EN 455-2 Physical Properties</li> <li>BS EN 455-3 Biological Evaluation</li> <li>BS EN 455-4 Shelf Life Determination</li> </ul>	

HPC Healthline UK Limited hereby declares that the above mentioned product meets the provisions of the Council Directive 93/42/EEC for Medical devices, as amended by directive 2007/47/EC and requirements of the BS EN 455 series of standards.

Signature:

David Greenwood

Name:

Position:

Director

Place of Issue: Date:

Morden, UK 15<sup>th</sup> June 2016

File Ref:

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Date of Issue:

HPC Healthline UK Ltd, Colwood House, 158 Garth Road, Morden, Surrey, SM4 4LZ, United Kingdom