

EC Declaration of Conformity

HPC Healthline UK Ltd declares that the PPE described hereafter:

Handsafe Lightly Powdered Latex Examination Glove (GN03)

- » 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:

Signature:



Name: Scott Prichard

Place of Issue: Morden, UK

Position: Director

Date: 09 June 2015

File Ref: HPC-DOC- 024 GN03 PPE

Revision: 2

Date of Issue: 09/06/2015

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Declaration of Conformity

Manufacturer: HPC Healthline UK Limited, Colwood House,
158 Garth Road, Morden, Surrey, SM4 4LZ, UK.

Product: GN03 Lightly Powdered 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: Medical gloves for single use:

- BS EN 455-1 Freedom from Holes
- BS EN 455-2 Physical Properties
- BS EN 455-3 Biological Evaluation
- BS EN 455-4 Shelf Life Determination

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.

Signature:



Name: David Greenwood

Place of Issue: Morden, UK

Position: Director

Date: 15th June 2016

File Ref: HPC-DOC-080 GN03 MDD

Revision: 4

Date of Issue: 15/06/2016

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Food Contact - Declaration of Conformity

For materials intended to come into contact with food

Manufacturer: HPC Healthline UK Ltd, Colwood House,
158 Garth Road, Morden, Surrey, SM4 4LZ

Product: GN03 Powder Free Latex Examination Gloves

Brand Name: Handsafe

HPC Healthline UK Ltd hereby declares that the above mentioned products are in compliance with the rules of:

- Regulation (EC) 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food.

and meet the demands of:

- Commission Regulation (EU) No 10/2011 of the Commission of 14 January 2011 on materials and articles made of plastic which are intended to come into contact with food.

and were examined under the OEM brand according to:

- Commission Regulation (EU) No 10/2011 of 14 January 2011 and Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on plastic materials and articles intended to come into contact with food.
- EN1186-1:2002 for test method (materials and articles in contact with foodstuffs – plastics) – overall migration.

The Handsafe GN03 powdered latex gloves are permitted for contact with the following specific food types:

» Aqueous foods » Fatty foods » Acidic foods » Dry foods

They are **not** permitted for use with: » Alcoholic foods

This declaration is supported by Test Report:

» S08CHM04969-WLL, issued by TUV Singapore.



Karen Gunning
QA and Regulatory Affairs Manager

28th November 2013

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File Ref: HPC-DOC-160
Date of Issue: 28/11/2013

Revision: 1
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