

Declaration of Conformity

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

Product: GN90 Powder Free Blue Nitrile Medical Examination Glove

Brand Name: Newton / 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 meets 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 and requirements of the BS EN 455 series of standards.

Signature:



Name: David Greenwood

Place of Issue: Morden, UK

Position: Director

Date: 13th June 2016

File Ref: HPC- DOC- 001 GN90 MDD

Revision: 4

Date of Issue: 13/06/2016

Page: Page 1 of 1

EC Declaration of Conformity

HPC Healthline UK Ltd declares that the PPE described hereafter:

Newton Handsafe Powder Free Blue Nitrile Examination Glove (GN90)

- » 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 585142 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: David Greenwood

Place of Issue: Morden, UK

Position: Director

Date: 21st July 2016

File Ref: HPC-DOC-038 GN90 PPE

Revision: 3

Date of Issue: 21/07/2016

Page: Page 1 of 1