

## EC Declaration of Conformity

HPC Healthline UK Ltd declares that the PPE described hereafter:

Handsafe Lightly Powdered Stretch Vinyl Examination Glove (GN51)

- » 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 585143 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: 14<sup>th</sup> July 2016

File Ref: HPC-DOC-028 GN51 PPE

Revision: 3

Date of Issue: 14/07/2016

Page: Page 1 of 1



## Declaration of Conformity

---

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

**Product:** GN51 Lightly Powdered Stretch Vinyl 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 Ltd 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:**

A handwritten signature in black ink, appearing to read 'D Greenwood'.

**Name:** David Greenwood

**Place of Issue:** Morden, UK

**Position:** Director

**Date:** 14<sup>th</sup> July 2016

**File Ref:** HPC-DOC-357 GN51 MDD

**Revision:** 1

**Date of Issue:** 14/07/2016

**Page:** Page 1 of 1