

# EC Declaration of Conformity



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

**Product:** GN91 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 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 and requirements of the BS EN 455 series of standards.

**Signature:**

**Name:** Scott Prichard

**Place of Issue:** Morden, UK

**Position:** Director

**Date:** 4<sup>th</sup> December 2013

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**Page:** Page 1 of 1



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