

## **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:** 1<sup>st</sup> June 2015

File Ref: HPC-DOC- 003 GN91 MDD Revision: 4

**Date of Issue:** 01/06/2015 **Page:** Page 1 of 1