EC Declaration of Conformity



Manufacturer: HPC Healthline UK Limited, Colwood House,

158 Garth Road, Morden, Surrey, SM4 4LZ, UK.

Product: GN830 Powder Free Long Cuff Blue Nitrile 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 ANNEX VII: Self declaration that the products of this

Assessment Route: 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: Date: 29th October 2013

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BS EN ISO 9001 IS 35557 BS EN ISO 13485 MD 7945 BS EN ISO 14001 EMS 580914



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