

## Declaration of Conformity

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

**Product:** GS21 Sterile Powder Free Latex Medical  
Examination Glove

**Brand Name:** Handsafe

**Classification:** Class I Sterile (According to Annex IX, Rule 5 of Council Directive  
93/42/EEC, as amended by directive 2007/47/EC).

**Conformity  
Assessment Route:** ANNEX V: Production Quality Assurance

**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

Sterilization of health care products:

- BS EN ISO 11137 series of standards

Healthline Medical 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 and BS EN ISO 11137 series of standards.

**Signature:**



**Name:** Scott Prichard

**Place of Issue:** Morden, UK

**Position:** Director

**Date:** 30<sup>TH</sup> July 2015

**File Ref:** HPC-DOC-196 GS21 MDD

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