

Declaration of Conformity

Distributor: Healthline Medical Limited, Colwood House, 158 Garth Road, Morden, Surrey, SM4 4LZ, UK.

Product: GX670 Powder Free Clear Vinyl Medical Examination Glove

Brand Name: Safedon

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: 20th May 2015

File Ref: HPC-DOC- 304 GX670 -MDD

Revision: 1

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