

## Statement of Conformity


<b>Distributor:</b>	Polyco Healthline Ltd.
<b>Distributor Address:</b>	South Fen Road, Bourne, Lincolnshire, PE10 0DN, UK.
<b>Product Brand:</b>	Finessis
<b>Product Description:</b>	Latex powder free sterile surgical glove
<b>Product Code:</b>	GSFP and GSFPU
<b>Medical Device Category:</b>	Class IIa Sterile
<b>Conformity Route:</b>	ANNEX V: Product Quality Assurance

**It is confirmed that the above product:**

### Medical:

is in conformity with the provisions of Council Directive 93/42/EEC on medical devices and with National Standards transposing harmonised standards EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, (Medical gloves for single use) BS EN ISO 11137-1:2015, BS EN ISO 11137-2:2015 (Serialisation of healthcare products) and is a Class IIa sterile medical device (according to Annex IX rule 7).

This statement of conformity based upon the manufacturer EC certificate.

Signed for and on behalf of: Polyco Healthline  
Place and date of issue: Bourne, 31<sup>st</sup> March 2020  
Name and role: David Langridge, Head of Technical  
Signature:   
Expiry Date: 10<sup>th</sup> June 2020