

## EC Declaration of Conformity

|                                 |   |
|---------------------------------|---|
| <b>Manufacturer:</b>            | Polyco Healthline Ltd.                              |
| <b>Manufacturer's Address:</b>  | South Fen Road, Bourne, Lincolnshire, PE10 0DN, UK. |
| <b>Product Brand:</b>           | HandSafe  |
| <b>Product Description:</b>     | Black latex powder free examination glove           |
| <b>Product Code:</b>            | GN39  |
| <b>Medical Device Category:</b> | Class I   |
| <b>Conformity Route:</b>        | Annex VII self-declaration                          |

### It is declared 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, and is self-certified as a Class 1 non-sterile medical device in accordance with Annex IX, rule 5.

This EC declaration of conformity is issued under the sole responsibility of the manufacturer, Polyco Healthline Ltd.

Signed for and on behalf of: Polyco Healthline Ltd  
Place and date of issue: Bourne, 22<sup>nd</sup> March 2019  
Name and role: David Langridge, Laboratory and Technical Manager  
Signature: 