

EU Declaration of Conformity

Manufacturer:	HPC Healthline UK LTD (Polyco Healthline)
Manufacturer's Address:	South Fen Road, Bourne, Lincolnshire, PE10 0DN, UK.
Product Brand:	HandSafe
Product Description:	Clear co-polymer powder free sterile glove
Product Code:	GS641
Medical Device Category:	Class I sterile
Conformity Route:	ANNEX V: Production Quality Assurance

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 455-3:2015, (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 1 sterile medical device (according to Annex IX rule 5).

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

Signed for and on behalf of: HPC Healthline UK Ltd (Polyco Healthline)
Place and date of issue: Bourne, 23rd July 2020
Name and role: David Langridge, Head of Technical
Signature: 
Expiry Date: 26th May 2024