

EU Declaration of Conformity

Manufacturer:	HPC Healthline UK Ltd.
Manufacturer's Address:	South Fen Road, Bourne, Lincolnshire, PE10 0DN, UK.
Product Brand:	Hand Safe
Product Description:	Blue Nitrile powder free sterile examination glove
Product Code:	GS690
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 455-2:2015, 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 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
Place and date of issue: Bourne, 03rd June 2020
Name and role: Karen Gunning, QARA Manager
Signature:



Expiry Date: 26th May 2024