

EU Declaration of Conformity


Manufacturer:	Polyco Healthline Ltd.
Manufacturer's Address:	South Fen Road, Bourne, Lincolnshire, PE10 0DN, UK.
Product Brand:	Synthesis
Product Description:	Natural polyisoprene sterile surgical gloves
Product Code:	GSSYN
Medical Device Category:	Class IIa Sterile
Conformity Route:	ANNEX V: Product 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 IIa sterile medical device (according to Annex IX rule 7).

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

Signed for and on behalf of: Polyco Healthline
Place and date of issue: Bourne, 17th March 2020
Name and role: David Langridge, Head of Technical
Signature: 
Expiry Date: 26th May 2024