


# EC Declaration of Conformity



We declare that the below mentioned product meets the provisions of EC Council Directive 93/42/EEC of 14<sup>th</sup> June 1993 concerning medical devices as amended by Directive 2007/47/EC.

All supporting documentation is retained under the premises of the manufacturer and notified body.

<b>MANUFACTURER ADDRESS</b>	Globus (Shetland) Ltd T2 Trafford Point Twining Road Trafford Park Manchester M17 1SH			
<b>BRAND</b>				
<b>PRODUCT</b>	Syntis PX Surgical Gloves • Synthetic, Non-Latex, Micro Textured Sterile • Powder Free			
	Product Codes:			
	Size 5½	HAK7055	Size 7½	HAK7075
	Size 6	HAK7060	Size 8	HAK7080
	Size 6½	HAK7065	Size 8½	HAK7085
	Size 7	HAK7070	Size 9	HAK7090
<b>CLASSIFICATION (MDD 93/42, ANNEX IX)</b>	IIa (Rule 7)			
<b>CONFORMITY ASSESSMENT</b>	Annex V, Annex VII			
<b>STANDARDS</b>	ISO 9001, ISO 13485, ISO 15223-1			
<b>NOTIFIED BODY</b>	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam			
<b>START OF CE-MARKING AND MDD COMPLIANCE</b>				

The product is intended to be used in surgical work and to be worn once and then discarded. Surgical glove is worn on the hand of surgeon and healthcare personnel to prevent contamination between healthcare personnel and the patient's body, fluids, waste or environment.

The gloves are designed for short-term use and are intended to be used in conjunction with invasive procedures.

Manchester, United Kingdom

**Andrew Morris**  
Management Representative