EC Declaration of Conformity

We declare that the below mentioned product meets the provisions of EC Council Directive 93/42/EEC of 14th 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.

MANUFACTURER ADDRESS	Globus (Shetland) Ltd T2 Trafford Point Twining Road Trafford Park Manchester M17 1SH			
BRAND	HAIKA			
PRODUCT	Syntis PX Surgical Gloves • Synthetic, Non-Latex, Micro Textured Sterile • Powder Free			
	Product Codes:			
	Size 5½ Size 6 Size 6½ Size 7	HAK7055 HAK7060 HAK7065 HAK7070	Size 7½ Size 8 Size 8½ Size 9	HAK7075 HAK7080 HAK7085 HAK7090
CLASSIFICATION (MDD 93/42, ANNEX IX)	IIa (Rule 7)			
CONFORMITY ASSESSMENT	Annex V, Annex VII			
STANDARDS	ISO 9001, ISO 13485, ISO 15223-1			
NOTIFIED BODY	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam			
START OF CE-MARKING AND MDD COMPLIANCE	18/10/2019			

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.

EU Representative:
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