

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	INTRA Surgical Green Undergloves • Latex • Sterile Powder Free			
	Product Codes:			
	Size 5½	HAK6055	Size 7½	HAK6075
	Size 6	HAK6060	Size 8	HAK6080
	Size 6½	HAK6065	Size 8½	HAK6085
	Size 7	HAK6070	Size 9	HAK6090
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 Kitemark Court Davy Avenue, Knowlhill Milton Keynes, MK5 8PP United Kingdom			
START OF CE-MARKING AND MDD COMPLIANCE	21/11/2018			

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