EC Declaration of Conformity

We herewith 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 Building 14 Central Park Mosley Road Trafford Park Manchester M17 1NY
BRAND	HAIKA
PRODUCT	INTRA Sterile Latex Surgical Green Undergloves, Powderfree Catalogue No.s HAK6055 – HAK6090 in increments of 5
CLASSIFICATION (MDD 93/42, ANNEX IX)	IIa (Rule 7)
CONFORMITY ASSESSMENT	Annex II excluding 4
STANDARDS	ISO 9001
NOTIFIED BODY	BSI Kitemark Court Davy Avenue, Knowlhill Milton Keynes, MK5 8PP United Kingdom
START OF CE-MARKING AND MDD COMPLIANCE	October 2014

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 transient use and are intended to be used in conjunction with invasive procedures.

Manchester, United Kingdom, 16th October 2014

Andrew Morris
Management Representative

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