

# 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.

<b>MANUFACTURER ADDRESS</b>	Globus (Shetland) Ltd T2 Trafford Point Twining Road Trafford Park Manchester M17 1SH		
<b>BRAND</b>	<b>HAIKA</b>		
<b>PRODUCT</b>	NX 484 Examination Glove		
	Product Code:		
	HAK4841 HAK4842 HAK4843	Size - S Size - M Size - L	
<b>CLASSIFICATION (MDD 93/42, ANNEX IX)</b>	Class I (Rule 4)		
<b>CONFORMITY ASSESSMENT</b>	Annex VII		
<b>STANDARDS</b>	EN455-1:2006, EN455-2:2009+A1:2011 & EN455-3:2006		
<b>NOTIFIED BODY</b>	N/A		
<b>START OF CE-MARKING AND MDD COMPLIANCE</b>	28/01/2021		

Manchester, United Kingdom

**Andrew Morris**  
Management Representative