


# 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>PRODUCT</b>	MX IIR Medical Mask			
	HAK8000 HAK8001	HAK8002 HAK8003		
<b>CLASSIFICATION (MDD 93/42, ANNEX IX)</b>	Class I (Rule 1)			
<b>CONFORMITY ASSESSMENT</b>	Annex VII			
<b>STANDARDS</b>	EN14683:2019			
<b>NOTIFIED BODY</b>	N/A			
<b>START OF CE-MARKING AND MDD COMPLIANCE</b>	11/09/2020			

Manchester, United Kingdom

**Christian Halford**  
Management Representative