


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.

MANUFACTURER ADDRESS	Globus (Shetland) Ltd T2 Trafford Point Twining Road Trafford Park Manchester M17 1SH
BRAND	
PRODUCT	MX IIR Healthcare Mask
	Product Code: HAK8001
CLASSIFICATION (MDD 93/42, ANNEX IX)	Class I (Rule 1)
CONFORMITY ASSESSMENT	Annex VII
STANDARDS	EN14683:2019
NOTIFIED BODY	N/A
START OF CE-MARKING AND MDD COMPLIANCE	15/04/2020

Manchester, United Kingdom



Andrew Morris
Management Representative