

EU DECLARATION OF CONFORMITY



According to the Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices (MDR) and other applicable Union legislation listed within the declaration.

HAIKA
HAIKA MX IIR
HAK8005

Type IIR

Ear Loop Medical Face
Mask

UDI:
(01)05060855881198

The legal manufacturer

Globus (Shetland) Ltd
T2
Trafford Point
Twining Road Trafford Park
Manchester
M17 1SH
UK
SRN GB-MF-000007834

Authorised (EU) Representative

Globus EMEA Ltd
51 Dawson St Dublin
D02 AN25
Ireland
SRN IE-AR-000002785

confirms that the listed product(s)

Conform(s) to

Regulation (EU) 2017/745 (Medical Devices
Regulation) as amended (effective from 26/05/2021)

And harmonised standard(s)

EN ISO 14971:2019
EN ISO 15223-1:2016
EN 1041:2008
EN ISO 10993-1:2020
EN 14683:2019

Intended Purpose

Protect health professionals during medical
procedures to prevent airborne transmission of
infections in patients and the treating personnel.

Risk Class

Class I

Classification Rule

Rule 1

Sterile

No

Measuring Function

No

Reusable

No

Conformity Assessment Route

This EU Declaration of Conformity is issued in
accordance with **Article 19** of Regulation (EU)
2017/745 (MDR). The conformity assessment has
been performed as a self-certification following the
procedure set out in **Article 52(7)** and **Annex IV** of the
MDR.

The Technical Documentation required by **Annex
II** and **Annex III** is available and maintained by the
manufacturer.

Signed on behalf of the manufacturer

J.Magniez

Head of Regulatory & Quality

27/02/2026


This EU declaration of conformity is issued under the sole responsibility of the manufacturer

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 Medical Mask | | | |
| | HAK8000 HAK8001 | HAK8002 HAK8003 | | |
| 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 | 11/09/2020 | | | |

Manchester, United Kingdom

Christian Halford
Management Representative