

EU DECLARATION OF CONFORMITY

(In accordance with EN ISO/IEC 17050-1)

Declaration number: **DOCIP 117571**
Name and address of manufacturer / EU-AR: **Medz Europe BV
Wiekenweg 41
3815 KL Amersfoort
Netherlands**



THIS DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF:

Name and address of manufacturer: **Medz Europe BV
Wiekenweg 41
3815 KL Amersfoort
Netherlands**

Product identification: **Merbach face masks Type IIR 50pcs, various colours**

Colour	Product code	EAN dispenser	EAN Outer Case
Blue	401102	8718164461026	8718164465024
White	401103	8718164461033	8718164465031
Pink	401104	8718164461040	8718164465048
Yellow	401105	8718164461057	8718164465055
Purple	401106	8718164461064	8718164465062
Black	401107	8718164461071	8718164465079
Green	401111	8718164461118	8718164465116

THE PRODUCTS MENTIONED IN THIS DECLARATION ARE IN CONFORMITY WITH:

EU Community Legislation **Medical Devices Directive (MDD) 93/42/EEC [OJEU L169/1-43, 12.07.1993]**

Harmonised standards **Medical devices**
EN 980:2008
EN 14683:2005 + EN 14683:2014
EN ISO 13485:2012 + AC:2012
EN ISO 14971:2012

Other specifications:

Notified Body:

Additional information: **Facemask 3-PLY with earloops and flexible nose fitting**

- Manufactured conform: EN14683
- TYPE IIR
- Filtration > 99%
- This product contains no latex
- Fiberglass free
- Hypoallergenic

SIGNED FOR AND ON BEHALF OF:

Place and date of issue: **Amersfoort, 30 November 2021**

Signature:

Name, function: **D.P.J. Schmits, Operational Director**

N.S. van Voorst, Management Assistant

Company name: **Medz Europe BV**

Medz Europe BV