



## DECLARATION OF CONFORMITY

We:

ViriMask Ltd. 4 Etgar St., Tirat Carmel, Israel 3910302

DECLARE ON OUR OWN RESPONSIBILITY THAT THE MEDICAL DEVICES:

### **Protective Oculo-Respirator Device, Face Mask with Eye Shield**

<b>Catalog Number #</b>	<b>Product</b>	<b>Color</b>
VM-MASK-L-RD	Large ViriMASK™ Kit (mask frame and visor, 2 V60 Filters, head straps)	Red
VM-MASK-L-BL		Blue
VM-MASK-L-BG		Beige
VM-MASK-M-RD	Medium ViriMASK™ Kit (mask frame and visor, 2 V60 Filters, head straps)	Red
VM-MASK-M-BL		Blue
VM-MASK-M-BG		Beige

MEET ALL APPLICABLE REQUIREMENTS OF THE MEDICAL DIRECTIVE 93/42/EEC ANNEX II, SECTION 3, INCLUDING THE AMENDMENTS OF THE MEDICAL DIRECTIVE 2007/47/EC.

**Classification** Class I respectively based on Annex IX, Rules 1 of the Medical Directive 93/42/EEC

**Applied standards** for the list of the applicable standards and other normative Documents, please refer to the Technical File.

**Conformity assessment procedures** MDD, Annex VII.

**Quality system** This declaration is supported by the Quality System certification based on the harmonized standards ISO 13485:2016.

**Representative in EU** MedNet ECREP GmbH, BorkstraBe 10 Munster 48163, Germany

Signed: ViriMask Ltd, Israel on May 2020