UK DECLARATION OF CONFORMITY

We,

Medicom Healthpro Ltd
Unit 1 Liliput Close, Brackmills Industrial Estate, Northampton, NN4 7EJ

Declare that the declaration of conformity is issued under our sole responsibility and relates to the following product:

Masks Op-Air® Pro FFP3 NR D – Type IIR
Respiratory mask without expiratory valve for single use
Category III PPE – Filtering half mask FFP3 NR D
Class I medical device – Medical face mask Type IIR
Basic UDI-DI: 37014074MAIIR52AQ
Product family: #52

Reference	Brand	Straps	Colour	Size	Option	Packaging
M53214-WH-UK	Kolmi	Headloops	White	Small	-	10 cartons of 50 units
M53214S-WH-UK	Kolmi	Headloops	White	Small	Individually packed	10 cartons of 50 units
M53014-WH-UK	Kolmi	Headloops	White	Medium	-	10 cartons of 50 units
M53014S-WH-UK	Kolmi	Headloops	White	Medium	Individually packed	10 cartons of 50 units
M53114-WH-UK	Kolmi	Headloops	White	Large	-	10 cartons of 50 units
M53114S-WH-UK	Kolmi	Headloops	White	Large	Individually packed	10 cartons of 50 units

PPE intended purpose: Single-use, non-sterile, respiratory FFP3 NR D filtering half mask, intended to cover the nose, the mouth and the chin of the user to protect him against solid particles and aerosols.

MD intended purpose: Single-use, non-sterile, medical face mask Type IIR, intended to cover the nose and the mouth of the healthcare professional and/or the patient during surgical procedures, medical cares or examinations, in order to prevent risk of cross-contamination and to protect the wearer against splashes of potentially contaminated liquids. Medical face masks may also be worn by patients or other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations.

The object of the declaration described above complies with the following legislations:

- Regulation (EU) 2016/425 on personal protective equipment
- Personal Protective Equipment (Enforcement) Regulations 2018
- Regulation (EU) 2017/745 medical devices

The following harmonised standards and technical specifications have been applied:

Personal Protective Equipment	Medical Device
EN 149:2001+A1:2009	EN 14683:2019

Conformity assessment procedure:

• Personal protective equipment:

The approved body INSPEC International UK. UKCA 0194 performed the UKCA type-examination (Module B) and issued the UKCA-type examination certificate n°UKCA-B-210742.

The PPEs are subject to the conformity assessment procedure conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the approved body INSPEC International UK. AB 0194.

• Medical device:

The product is subject to the procedure set out in Annex IV of Regulation (EU) 2017/745 and do not require an EU-type examination certificate by a notified body or approved body.

Name: Hugues Bourgeois

Place of issue: Northampton, UK

Function: Managing Director

Date of issue: V2 – 12/11/2021

Signature: