UKCA DECLARATION OF CONFORMITY

We,

GROUPE KOLMI HOPEN
Boulevard de la Chanterie - 49124 Saint-Barthélemy-d'Anjou – France

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

Op Air-Pro® Oxygen FFP2 NR D – Type IIR

Respiratory mask without expiratory valve for single use
Category III PPE – Filtering half mask FFP2 NR D
Class I medical device – Medical face mask Type IIR
Product family: #47

Reference	Brand	Links	Color	Size	Option	Packaging
M52214-WH	KOLMI	Headloops	White	S	-	10 boxes of 50 units
M52214S-WH	KOLMI	Headloops	White	S	Individually packed	10 boxes of 50 units

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.

PPE intended purpose: Single-use, non-sterile, respiratory FFP2 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.

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

- Regulation 2016/425 on personal protective equipment, as amended to apply in GB
- UK Medical Device Regulation 2002

The following harmonised standards and technical specifications have been applied:

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

Conformity assessment procedure:

- **Personal protective equipment:**

  The notified body APAVE (0082) performed the EU type-examination (Module B) and issued the EU-type examination certificate n° 0082/1467/079/11/21/0719.
  The product is subject to the conformity to type assessment procedure based on quality assurance of the production process (Module D) under surveillance of the notified body APAVE (0082).
  As stated by the UK government on November 14th 2022, products being CE marked by a notified body before December 31st 2024, do not require UKCA type examination certification by an Approved Body (UK). CE conformity assessment can be used as a basis for UKCA marking and the product can be placed on the UK market until the validity of the CE certificate expires or for three years (up to December 31st 2027).

- **Medical device:**

  The product is subject to the procedure set out in UK Medical Device Regulation 2002 and does not require a UKCA type examination certificate by an approved body.

Signed for and on behalf of: Sandrine ENGELS, President of Medicom Europe

Name: Yannick CHEVALIER

Place of issue: Saint Barthélemy d'Anjou

Function: R&D, Innovation & Regulatory Director

Date of issue: 13/02/2023

Signature: