KOLMI HOPEN
GROUP

UKCA DECLARATION OF CONFORMITY

We,

GROUPE KOLMI HOPEN SAS
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

Respiratory mask without expiratory valve for single use
Category III PPE – Filtering half mask FFP2 NR D
Product family: #55

Reference	Brand	Links	Color	Option	Packaging
M52015-WH	KOLMI	Headloops	White	-	10 boxes of 50 units
M52015S-WH	KOLMI	Headloops	White	Individually packed	10 boxes of 50 units

The object of the declaration described above complies with the Regulation 2016/425 on personal protective equipment, as amended to apply in GB.

The following harmonised standards and technical specifications have been applied: EN 149:2001+A1:2009

Conformity assessment procedure:

The notified body APAVE (0082) performed the EU type-examination (Module B) and issued the EU-type examination certificate n° 0082/1467/079/12/20/0816.
The PPE is subject to the conformity to type assessment procedure based on quality assurance of the production (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).

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: