

Technical Data Sheet

OP-air®

Earloops medical face mask

Flowpack packaging

Type IIR

Medical Device Class I

EN14683:2019+AC:2019



FEATURES & BENEFITS

- Protects the environment from droplets emitted by the wearer while providing protection from splashes of biological fluids.
- Effective against bacteria, particles and viruses (BFE, PFE, & VFE tested)
- Kolmi masks feature the exclusive Origami folding and Smile welding for greater comfort and a perfect fit on the wearer's face.
- For maximum comfort, the inner layer is designed with Softex technology to limit facial irritation and the wear and tear even with the beard.

Recommended use

- Use by medical staff
- Use by operating room staff in surgeries where there is a risk of biological fluids splashing
- Recommended for sensitive skin and beard wearers.
- Medical masks may also be intended to be worn by patients and other people to reduce the risk of spreading infection, particularly in epidemic or pandemic situations.

THE FLOWPACK ADVANTAGE

- Compact, hygienic and handy packaging.
- Easy take-out masks
- Earloops are folded under each mask and welded inside.
- Opening and closing with repositionable label

PRODUCT DETAILS

Product name :	Kolmi® OP-air® Type IIR
Item code :	M35111-32
Product type :	Single use, non sterile
Fasteners :	Earloops
Nose piece :	Polypropylene & metal
Qty per pack :	25 masks
Dimensions :	90 x 175 mm
Color :	Blue
Unit weight :	4 g (+/-10%)
Manufacturing country :	FRANCE



Filtration datas and comfort

TEST	STANDARD	REQUIRED LEVEL	LABORATORY	REPORT N° & DATE	AVERAGE RESULTS
Bacterial Filtration Efficiency : BFE	EN 14683:2019	≥ 98%	Nelson	1242388-S01 02/12/2019	98,8%
DELTA P	EN 14683:2019	< 60 Pa/cm ²	Centexbel	20.01944.01 24/04/2020	20,9 Pa/cm ²
SPLASH RESISTANCE	EN 14683:2019	≥ 16 kPa	Nelson	1249695-S01 18/12/2019	Compliant
Particles Filtration Efficiency 0,1µm : PFE	/	Not required	Nelson	1393998-S01 01/03/2021	99,8 %
Viral Filtration Efficiency: VFE	/	Not required	Nelson	1362437-S01 12/11/2020	98,4 %

BIOLOGICAL EVALUATION ACCORDING TO EN 14683:2019

- No cytotoxicity - Nelson report n°1030858-S01 dated 22/03/2018
- Non-irritant - Namsa report n°231037 dated 21/06/2017
- Non-sensitising - Namsa report n°231038 dated 19/07/2017

MICROBIOLOGICAL INFORMATION

Assessment of initial microbial contamination according to standards EN 14683: 2019 and ISO 11737: 2018
 Additional microbiological controls: ASR, E.coli, Staphylococci, available upon request.

CERTIFICATIONS & STANDARDS

Complies with the requirements of Regulation (EU) 2017/745 relating to Medical Devices
 Complies with applicable harmonized standards EN 14683
 Manufacturing site: ISO 9001 et ISO 13485

PRECAUTIONS

The device should only be used on clean, healthy skin.
 Their re-use or prolonged use can produce infection or cross-contamination.
 After use, comply with the national regulations in force for the disposal of the device.

STORAGE

Normal conditions of conservation and storage: must not be exposed to humidity and sun, must be stored at a temperature between 5°C and 40°C.
 Product life: 5 years.

MARKING ON PACKAGING



LOGISTICS

Outer case spec.					Flowpack spec			
Item	Size (mm)	Grosse Weight (kg)	QTY / pallet	BARCODE	Size (mm)	QTY / Case	Flowpack gross weight	BARCODE
M35111-32	550 x 215 x 215	2,5	56 Cases	3 662 036 018 762	245 x 100 x 55	20 flowpacks of 25 masks	100 g	3 662 036 018 779