Medicom
Kolmi®
Feeldry

Technical Data Sheet

M34001-40
M34101-40
M34201-40

Medical mask with ties-on - Type IIR - Kolmi® Feeldry

Medical Device Class I

DOMINIQUE DUTSCHER SAS

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)
- Kolmi masks feature the exclusive Origami folding for greater comfort and a perfect fit on the wearer's face.
- Featuring a wide and ultra-flexible nose strip, they ensure an excellent fit to the face and effectively limit leakage around the nose, thereby significantly reducing fogging.
- For maximum comfort, the inner layer is designed with a material that limits irritation to the face.
- With Feeldry technology the inner layer has been specially designed to absorb perspiration and avoid the feeling of humidity inside the mask.
- Hypoallergenic
- **NEW PACKAGING : Each tie-on is folded under each mask for convenient and tidy single removal.**

RECOMMENDED USE

- Use by medical staff.
- Use by operating room staff for surgeries with a risk of biological fluid splashes.

PRODUCT DETAILS

Product name :	Kolmi® Feeldry Type IIR
Product type :	Single use, non sterile
Fasteners :	Ties-on
Nose piece :	Polypropylene and steel
Size :	95 x 175 mm
Unit weight :	4,7 g
Quantity / box :	50 masks
Origin :	France

Item	Color
M34001-40	White
M34101-40	Blue
M34201-40	Green

CERTIFICATIONS & STANDARDS

Meet the requirements of Regulation (EU) 2017/745 on medical devices.
Meets applicable requirements of EN 14683:2025*.
Manufacturing site: ISO 9001 and ISO 13485 certification.

MICROBIOLOGICAL INFORMATION

Assessment of initial microbial contamination according to standards EN 14683:2025* & ISO 11737: 2018+A1:2021.
Additional microbiological controls: ASR, E.coli, Staphylococci, available upon request.

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EN 14683:2025*					
TEST	STANDARD	REQUIRED LEVEL	LABORATORY	REPORT N° & DATE	AVERAGE RESULTS
Bacterial Filtration Efficiency : BFE	EN 14683:2025*	≥ 98% (Type IIR)	Centexbel	21.06133.02 25/10/2021	99,8 %
DELTA P	EN 14683:2025*	≤ 300 Pa	Centexbel	22.00530.08 22/02/2022	127 Pa
SPLASH RESISTANCE	ISO 22609:2004	≥ 16 kPa	Centexbel	22.00530.09 22/02/2022	Conform
Particles Filtration Efficiency 0,1 µm : PFE	ASTM F2299	No requirements	Nelson	1362445-S01 03/12/2020	99,5 %
Viral Filtration Efficiency : VFE	ASTM F2101	No requirements	Nelson	1362444-S01 22/12/2020	99,4 %

* based on testing to EN14683:2019 + AC:2019

PRECAUTIONS

The mask must be used on intact skin only.
The reuse or extended use may lead to infection or cross-contamination.
Please refer to your national legislation on the subject of disposal of this product once it has been used.

STORAGE CONDITIONS

Normal conditions of conversation & storage: not to be exposed to moisture and sunlight, must be stored at room temperature.
Shelf life of the product: 5 years.

PACKAGING MARKING

CE MD Medical Device LATEX *

* Do not use if package is damaged

LOGISTICS

Outer case Spec.

Item	Size (mm)	Gross weight (kg)	QTY/ pallet
M34001-40 M34101-40 M34201-40	400 x 400 x 178	2,1	54

Inner box spec.

Size (mm)	Gross weight (g)	Packaging
192 x 125 x 165	291	6 boxes x 50 masks

EAN Codes

Item	Outer case	Inner box
M34001-40	3 701 407 400 239	3 701 407 400 222
M34101-40	3 701 407 400 215	3 701 407 400 208
M34201-40	3 701 407 400 178	3 701 407 400 161

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