Technical Data Sheet

60.702-STE — Sterile clean room mask

With headloops - Origami folding

FEATURES & BENEFITS



- Sterilized with Ethylene Oxide (EO) - **Sterility Assurance Level 10^{-6}.**
- Compatible for use in **ISO 3 Class A or higher cleanrooms**. The mask has been tested using the Helmke Drum before and after sterilization = CAT 1.
- Easy to put on & enhanced comfort thanks to excellent breathability. Softex technology minimizes the risk of particulate contamination while reducing the risk of irritation for the wearer.
- The mask does not yellow and remains odorless even after sterilization.
- Wide facial coverage & optimal fit.
- High bacterial, viral, and particulate filtration efficiency**. Tested before and after sterilization, performance remains strictly identical.**
- Made from **50% recycled materials.**
- The ISO AIR range is manufactured in a Controlled Atmosphere Zone.

PRODUCT DETAILS

Product name :	Sterile clean room face mask
Product type:	Single use, sterile
Shape :	Origami folding
Fasteners :	Headloops
Packaging :	6 pouches of 50 masks – Double packaging with individual primary-level packaging Secondary-level packaging in sets of 50
Dimensions :	210 x 90 mm (+/- 5mm)
Weight :	4,8 g (+/- 10%)
Manufacturing country :	MADE IN FRANCE

Made from **50% recycled materials**, this ISO AIR mask reduces the consumption of polypropylene from fossil resources. Thanks to the Mass Balance approach and its value chain, we have designed the ISO AIR range from recycled polypropylene which, thanks to a chemical recycling process using heat, is returned to the state of monomers. This enables to keep the **same characteristics** as virgin polypropylene. It is thanks to this technique that our Mass Balance masks maintain **excellent performances**, similar to the performances of a mask made from virgin polypropylene.. For more information about Mass Balance, please contact us.

RECOMMENDED AREAS – GMP COMPLIANT

Micro & nanoelectronics / Aerospace / Laboratories / Research / Cosmetics / Medical devices / Biotechnology / Automotive

DOMINIQUE DUTSCHER SAS

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CERTIFICATIONS & STANDARDS

Helmke drum tested according to IEST-RP-CC003.4
Manufactured in an ISO 9001 certified facility
Sterilization according to ISO 11135:2014 standard governing the sterilization of health products with Ethylene Oxide.
This mask is neither a Medical Device within the meaning of Regulation (EU) 2017/745 nor a Personal Protective Equipment within the meaning of Regulation (EU) 2016/425.

MASK PERFORMANCE AFTER STERILIZATION				
TEST	TEST METHOD	LABORATORY	REPORT N° & DATE	RESULTS
DELTA P	EN 14683:2019	CENTEXBEL	23-01856-01 02/05/2023	31,2 Pa/cm²
Bacterial Filtration Efficiency BFE	EN 14683:2019	CENTEXBEL	23-01856-01 02/05/2023	> 99 %
Particulate Filtration Efficiency @0,1 µm : PFE	ASTM F2299	NELSON	1602270-S01 01/05/2023	> 99 %
Viral Filtration Efficiency : VFE	ASTM F2101	NELSON	1602271-S01 14/04/2023	> 99 %

STORAGE CONDITIONS

Normal storage conditions: should not be exposed to moisture and sunlight, should be stored at room temperature.

Shelf life after sterilization date: 5 years

LOGISTICS

Outer case spec.

Article	Size (mm)	Gross weight (kg)	QTY/ pallet
60.702-STE	580 x 380 x 250	3,5	28

Inner bag spec.

Size (mm)	Weight (g)	QTY / case
570 x 370 x 70	480	6 x 50

Codes EAN

Item	Outer case	Inner bag
60.702-STE	3 700 381 522 210	3 700 381 522 227

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