HOPEN® ALL OVER PROTECTION

Technical Data Sheet

60.702-STE Sterile clean room face mask
With headloops

ISO AIR®

FEATURES & BENEFITS



- Sterilised mask with Ethylène Oxide (ETO) > Sterility Assurance Level 10^{-6}.
- Suitable for use in ISO 3 Class A or higher environments. The mask has been Helmke drum tested before and after sterilisation > CAT 1.
- Easy to put on & more comfortable thanks to excellent breathability. Softex technology limits the risk of particulate contamination while reducing the risk of irritation for the wearer.
- The mask does not turn yellow and remains odourless even after sterilisation.
- Wide face coverage & optimal fit.
- High bacterial, viral and particulate filtration efficiency.
  > Tested before and after sterilisation, the performance remains strictly identical.

PRODUCT DETAILS

Product name :	Sterile clean room face mask
Product type:	Single use, sterile
Folding :	Origami
Fasteners :	Headloops
Packaging :	6 polybags of 50 masks - **Individual double packed in sterilisation pouches**
Dimensions :	210 x 90 mm (+/- 5mm)
Weight :	4,8 g (+/- 10%)
Manufacturing country :	France

KOLMI HOPEN · USES RECYCLED PLASTIC ·

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

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CERTIFICATIONS & NORMES

Helmke drum tested according to IEST-RP-CC003.4
Manufactured in an ISO 9001 certified facility in an ISO Type 8 clean room
Sterilisation according to ISO 1135:2014 standard governing the sterilisation 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 STERILISATION			
TEST	**TEST METHOD**	**LABORATORY**	**RESULTS**
DELTA P	EN 14683:2019	NELSON	30 - 35 Pa/cm² 3,05 - 3,56 mm H_20/cm²
Bacterial Filtration Efficiency BFE	EN 14683:2019	NELSON	> 99 %
Particulate Filtration Efficiency @0,1 µm : PFE	ASTM F2299	NELSON	> 99 %
Viral Filtration Efficiency : VFE	ASTM F2101	NELSON	> 99 %

STORAGE CONDITIONS

Normal storage conditions: should not be exposed to moisture and sunlight, should be stored at room temperature.
Shelf life after sterilisation date: 3 years

OUTER CASE SPEC.					INNER BAG SPEC.			
ITEM	**SIZE (mm)**	**GROSS WEIGHT (kg)**	**QTY / pallet**	**BARCODE Outer case**	**SIZE (mm)**	**WEIGHT (g)**	**QTY / outer case**	**BARCODE INNER BAG**
60.702-STE	580 x 380 x 250	3,5	28	3 700 381 522 210	570 x 370 x 70	480	6 x 50 = 300 pc	3 700 381 522 227

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