658391
Medical Face Mask Extra Protection

Product details

Descriptive feature: Cup-keeper, Soft, Tie-band, Type IIR
Color: White
Sterility: Non-sterile

Images

Delivered items

658391-01

Country of origin: Japan
Shelf life: 5 years
Sterilization method: Non-sterile
Packing information: First packaging layer is a paper board dispenser box. Second layer is a corrugated board transport box.

Packaging level	Pack count	GS1 code
Dispenser box	50	7323190000388
Transport box	500	7323190000371
Pallet	24000	7323190000364

Material

Animal tissues:

No

Human blood derivatives:

No

Medicinal substances:

No

Phthalates:

No

Polyvinyl chloride:

No

Product Performance Medical Face Masks

Characteristics	Test Method	Internal Test Method	Unit	Requirement	Product Performance
Bacterial filtration efficiency (BFE)	EN 14683, App B	N/A	%	≥98	Pass
Breathability	EN 14683, App C	N/A	Pa/cm²	<49.0	Pass
Splash resistance tested at 16kPa	ISO 22609	N/A	Pass/Fail	Less than 3 penetrations out of 32 tested	Pass
Microbial cleanliness	ISO 11737-1	T-303	CFU/g	≤30	Pass

Product Composition Medical Face Masks

Product Component	Composition
Outer facing	Polypropylene nonwoven
Inner facing	Polypropylene, Polyethylene
Filter medium	Polypropylene nonwoven
Insertion	Polypropylene nonwoven
Nose clip	Polyethylene covered steel

Product Component	Composition
Tie bands	Polypropylene nonwoven
Cup keeper	Polypropylene nonwoven
Anti-fog film	Polypropylene nonwoven coated with polyethylene film

Technical

Dimension

Dimension text	Dimension value
Length	180 mm
Width unfolded	180 mm
Width folded	90 mm
Length upper tie-band	430 mm
Length lower tie-band	380 mm
Nose clip	133 mm

Disposal instructions

Non-hazardous waste used BARRIER products and sterility barriers should, in the majority of cases, be classified as non-hazardous waste. They contain high amounts of energy and are well suited for incineration. BARRIER products do not contain any hazardous substances that can leach out if the products are land filled. Transport boxes are designed to fit existing recovery systems. The new BARRIER packaging system complies with the Packaging Waste Directive of the European Union.

Storage instructions

Mölnlycke Health Care recommends that BARRIER products are stored under normal storage conditions. All layers of packaging should be kept intact until access to the underlying layers is needed. Storage facilities for products only protected by the sterility barrier should be kept under conditions where low level of particulate air contamination prevail, so that it would not constitute a risk to the patient when the package is opened and the product is used.

Classification

Regulation type	MDD Class I
MDD Classification Rule:	1

Regulation type	**MDD Class I**
Intended use MDD:	The device is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate matter.

Applied standards: The standards presented below is a selection of the most essential standards that are adhered to.

EN 1041, EN 14683, EN 62366, EN ISO 9001, EN ISO 13485, EN ISO 10993-1, EN ISO 10993-5, EN ISO 15223-1, ISO 15223-2, EN ISO 10993-10, ISO 14001

Removable Label

No

GMDN Code (Global Medical Device Nomenclature)

35177

Reusability

Single use