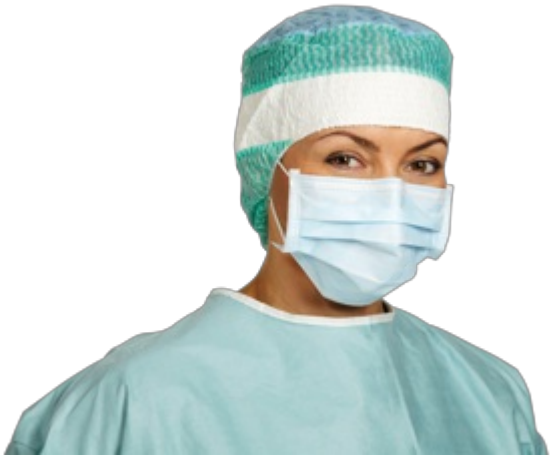
4315 Medical Face Mask Extra Protection

Medical Face Mask

Product details

Size : One size
Descriptive feature : Ear Loop, Type IIR
Colour : Blue
Sterile : Non-sterile

Images



Delivered items

4315-00

Country of origin: China
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.
Is suitable for Tray: No

Packing level	Quantity	GS1 code	WxLxH (mm)	Vol (dm3)	Weight gross/net (kg)
Dispenser box	50	7332551878733	100x185x85		
Transport box	600	7332551878726	318x381x178	21.6	3.0 / 2.1
Pallet	32400	7332551878719	800x1200x1747		

Material

Mölnlycke Health Care AB, Box 13080, Gamlestadsvägen 3 C, SE-402 52 Göteborg, Sweden. Phone +46 31 722 30 00.
The Mölnlycke trademarks, names and logotypes are registered globally to one or more of the Mölnlycke Health Care Group of Companies.
©2021 Mölnlycke Health Care AB. All rights reserved.

Animal tissues :	No
Human blood derivatives :	No
Natural rubber latex :	No
Medicinal substances :	No
Phthalates :	No
Polyvinyl chloride :	No

Product Composition Medical Face Masks

Product Component	Composition
Outer facing	Polypropylene nonwoven
Inner facing	Polyethylene, Polyester
Filter medium	Polypropylene nonwoven
Insertion	Polypropylene nonwoven
Nose clip	Polyethylene covered steel
Ear loops	Polyurethane, Polyamide (Nylon)

Product Performance Medical Face Masks, Type IIR

Characteristics	Test Method	Internal Test Method	Unit	Requirement	Product Performance
Bacterial filtration efficiency (BFE)	EN 14683 (Annex B)	N/A	%	≥98	≥ 99
Differential pressure	EN 14683 (Annex C)	N/A	Pa/cm²	<60	26-36
Splash resistance pressure	ISO 22609	N/A	kPa	≥16.0 Less than 3 penetrations out of 32 tested	31 of 32 pass at 16 kPa
Microbial cleanliness	ISO 11737-1	T-303	CFU/g	≤30	0-10

Technical

Dimension

Dimension text	Dimension value
Length	180 mm
Width unfolded	170 mm
Width folded	95 mm
Length ear-loop (unstretched)	155 mm
Nose clip	130 mm

Mölnlycke Health Care AB, Box 13080, Gamlestadsvägen 3 C, SE-402 52 Göteborg, Sweden. Phone +46 31 722 30 00.
The Mölnlycke trademarks, names and logotypes are registered globally to one or more of the Mölnlycke Health Care Group of Companies.
©2021 Mölnlycke Health Care AB. All rights reserved.

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.

Classifications

Regulation type(s)	MDD Class I	Locally Regulated	Unregulated
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.		
MDD Classification Rule :	1		
Conformity Annexes :	VII		
Measuring Function :	No		
Regulatory released :	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Faroe Islands, Finland, France, Germany, Gibraltar, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Netherlands Antilles, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom of Great Britain and Northern Ireland	Albania, Algeria, Armenia, Australia, Bahrain, Congo, Congo (the Democratic Republic of the), Egypt, Israel, Japan, Jordan, Korea (the Republic of), Kuwait, Lebanon, Macao, Malaysia, Mexico, Moldova (the Republic of), Morocco, New Zealand, Oman, Pakistan, Qatar, Russian Federation, Saudi Arabia, Serbia, Sudan, Taiwan (Province of China), Thailand, Tunisia, Turkey, United Arab Emirates	Barbados, Bermuda, Bosnia and Herzegovina, Chile, Côte d'Ivoire, Djibouti, Ethiopia, Gabon, Georgia, Hong Kong, Iran (Islamic Republic of), Iraq, Kenya, Libya, Macedonia (the former Yugoslav Republic of), Malawi, Mauritius, Montenegro, Nigeria, Sierra Leone, Singapore, South Africa, Syrian Arab Republic, Tanzania, United Republic of, Uganda, Venezuela (Bolivarian Republic of), Yemen

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

Mölnlycke Health Care AB, Box 13080, Gamlestadsvägen 3 C, SE-402 52 Göteborg, Sweden. Phone +46 31 722 30 00.
The Mölnlycke trademarks, names and logotypes are registered globally to one or more of the Mölnlycke Health Care Group of Companies.
©2021 Mölnlycke Health Care AB. All rights reserved.

GMDN Code (Global Medical Device Nomenclature)

35177 Surgical face mask, single-use

Reusability

Single use

UNSPSC

42131713 Surgical isolation or surgical masks

Commodity Code

6307909810 Face masks nonwoven

Mölnlycke Health Care AB, Box 13080, Gamlestadsvägen 3 C, SE-402 52 Göteborg, Sweden. Phone +46 31 722 30 00.
The Mölnlycke trademarks, names and logotypes are registered globally to one or more of the Mölnlycke Health Care Group of Companies.
©2021 Mölnlycke Health Care AB. All rights reserved.