42904 FILTERING HALF MASK

Medical Face Mask

Product details

Sterile : Non-sterile
Brand : BARRIER

Images

Delivered items

42904-00

Sales released in: Australia, Austria, Azerbaijan, Bahrain, Belgium, Chile, Colombia, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, French Polynesia, Germany, Greece, Hong Kong, Hungary, Iceland, India, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Malta, Martinique, Mexico, Morocco, Netherlands, Norway, Poland, Portugal, Romania, Saudi Arabia, Serbia, Singapore, Slovenia, Spain, Sweden, Switzerland, United Kingdom of Great Britain and Northern Ireland
Country of origin: Japan
Shelf life: 3 years
Sterilization method: Non-sterile
Production Responsibility: San-M Package Co. Ltd., 1086-1 Ojiro, Shimada-city, Shizuoka, 428-0009 Japan
Packing information: First packaging layer is a paper board dispenser box. Second layer is a corrugated board transport box.
Is suitable for Tray: Yes

Packing level	Quantity	GS1 code	Width x Length x Height	Vol	Weight gross / net
Transport box	200	7332430385703	261x368x178 mm	17.1 dm3	2.0 / 1.4 kg

Packing level	Quantity	GS1 code	Width x Length x Height	Vol	Weight gross / net
Pallet	16200	7332430451637	800x1200x1815 mm		

Material

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

Product Composition Filtering Half Mask

Product Component	Composition
Outer facing	Polypropylene nonwoven
Inner facing	Polyester
Filter medium	Polypropylene nonwoven
Nose clip	Aluminium
Head harness	Polyurethane (head band)

Product Performance Filtering Half Mask FFP2

Characteristics	Test Method	Internal Test Method	Unit	Requirement	Product Performance
Bacterial filtration efficiency (BFE)	SS-EN 14683:2019+AC:2019, Type II	External Test	%	≥98	>99,9%, no colonies detected
Breathing resistance Inhalation 30 l/min	EN 149+A1:2009 FFP2	External Test	mbar	≤0.7	Pass
Breathing resistance Inhalation 95 l/min	EN 149+A1:2009 FFP2	External Test	mbar	≤2.4	Pass
Breathing resistance Exhalation 160 l/min	EN 149+A1:2009 FFP2	External Test	mbar	≤3.0	Pass
Inward leakage, individual results (at least 46 of 50)	EN 149+A1:2009 FFP2	External Test	%	<11	Pass
Inward leakage, mean values (at least 8 of 10)	EN 149+A1:2009 FFP2	External Test	%	<8	Pass

Characteristics	Test Method	Internal Test Method	Unit	Requirement	Product Performance
Penetration of filter material (Sodium cloride test 95l/min and Paraffin oil test 95l/min)	EN 149+A1:2009 FFP2	External Test	%	≤6	Pass
Carbon dioxide content of inhalation air	EN 149+A1:2009 FFP2	External Test	%	≤1	Pass
Microbial cleanliness	SS-EN 14683:2019+AC:2019, Type II	External Test	CFU/g	≤30	Mean value: 0,22 CFU/g

Technical

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.

Storage conditions	Storage value
Low temperature in Celsius :	-20
High temperature in Celsius :	32
High humidity in percentage :	85

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Classifications

Regulation type(s)	Class I	MDR Class I ns	Locally Regulated	Locally Regulated
Intended Purpose :	The device is intended to be worn to protect the patient and/or user from the transfer of microorganisms, body fluids and particulate matter.	The device is intended to be worn to protect the patient and/or user from the transfer of microorganisms, body fluids and particulate matter.	The device is intended to be worn to protect the patient and/or user from the transfer of microorganisms, body fluids and particulate matter.	The device is intended to be worn to protect the patient and/or user from the transfer of microorganisms, body fluids and particulate matter.
MDR Classification Rule :		1		
Conformity Annexes :		IV		
Measuring Function :		No		
Other Union Legislation :	Personal Protective Equipment Directive 89/686/EEC	Personal Protective Equipment Directive 89/686/EEC	Personal Protective Equipment Directive 89/686/EEC	Personal Protective Equipment Directive 89/686/EEC
Notified body medical devices/PPE :	PMDA (Japan)	MPA	Local Authority India	Local Authority Mexico
Regulatory Released :	Japan	Austria, Belgium, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Martinique, Netherlands, Norway, Poland, Portugal, Romania, Slovenia, Spain, Sweden, Switzerland, United Kingdom of Great Britain and Northern Ireland	India	Mexico

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MDR Classification Rule :				
Conformity Annexes :				
Measuring Function :				
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Notified body medical devices/PPE :	Local Authority EU Non EEC	Local Authority APAC	Saudi Authority	Local Authority MEA
Regulatory Released :	Serbia	French Polynesia, Hong Kong, Singapore	Saudi Arabia	Bahrain, Morocco

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MDR Classification Rule :		
Conformity Annexes :		
Measuring Function :		
Other Union Legislation :	Personal Protective Equipment Directive 89/686/EEC	Personal Protective Equipment Directive 89/686/EEC
Notified body medical devices/PPE :	Local Authority Americas	Local Authority CIS
Regulatory Released :	Chile, Colombia	Azerbaijan

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

EN 149, EN 1041, EN 14683, EN 62366, EN ISO 9001, EN ISO 13485, EN ISO 10993-1, EN ISO 10993-5, EN ISO 15223-1, EN ISO 10993-10, ISO 14001, ISO 15223-2

GMDN Code (Global Medical Device Nomenclature)

57794 Surgical/medical respirator, non-antimicrobial, single-use

UNSPSC

42131713 Surgical isolation or surgical masks

Commodity Code

6307909311 FFP2 & FFP3 half mask in accordance with EN149

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