







COVID-19 - FACE MASKS COMPARATIVE TABLE FOR USE IN SURGICAL AND OPERATIVE MEDICAL PRACTICES



Type of Mask	Medical Device Surgical Mask EN 14683			PPE Mask for Particulate EN 149		FP5 SAFECOMFORT	(images for example only - features and shape may vary upon brand)
							
Class	Type I	Type II	Type IIR	FFP2	FFP3	MASK AGAINST COVID-19	Applicable Normative and Requirements
Certified "Face Mask against COVID-19"	NO	NO	NO	NO	NO	YES - DUAL CERTIFICATION: CE 0161 PPE-RFU/02.075-V2 + M.D. EN 14683 TYPE IIR	EN 14683 - EN 149 - RFU/02.075-V2
Suitable against COVID-19	NO	NO	YES IF USED OVER A FACE MASK FFP2-FFP3	YES IF USED UNDER A SURGICAL MASK TYPE IIR	YES IF USED UNDER A SURGICAL MASK TYPE IIR	YES*	*DPI-RFU/02.075-V2 CE 0161 + D.M.CE EN 14683 TIPO IIR
Registration in the Italian (EU) Ministry of Health Medical Device Repertory	Mandatory	Mandatory	Mandatory	Not Required	Not Required	YES - No. 1944143 / 1948544	EN 14683
Certification by Notified Body	Not Required	Not Required	Not Required	Mandatory	Mandatory	YES - CE 0161 No.2020/2803/00/0161	EN 149 - RFU/02.075-V2
Layers of the TNT in Polyester and/or in Polypropylene (spun bond - meltblow)	3 Layers	3 Layers	3 Layers with hydrophobic treatment	2-3 Layers	3-4 Layers	5 Layers of Polypropylene for Medical Applications Made in Germany	EN 14683 - EN 149 - RFU/02.075-V2
Type of elastic holding to the face	Earloops (fixed)	Earloops (fixed)	Earloops (fixed or adjustable)	Earloops (fixed)	Headloops (adjustable)	Model 88001 with Headloops adjustable - Model 88002 with Earloops fixed	EN 14683 - EN 149 - RFU/02.075-V2
BFE - Bacterial Filtration Efficiency (% max)	≥ 95	≥ 98	≥ 98	Not Required	Not Required	99.9	Requirements to be met according to EN 14683
Traspirability - Differential Pressure (Pa/cm2 max)	< 40	< 40	< 60	Not Required	Not Required	48.1	Requirements to be met according to EN 14683
Microbial Cleanless (cfu/g min)	≤ 30	≤ 30	≤ 30	Not Required	Not Required	12.0	Requirements to be met according to EN 14683
Splash Resistance Pressure (≤16 kPa)	Not Required	Not Required	YES	Not Required	Not Required	CONFORM	Requirements to be met according to EN 14683
Biocompatibility Hypoallergenic Tests	YES	YES	YES	Not Required	Not Required	CONFORM	Requirements to be met according to EN 10993
Citotoxicity in Vitro	YES	YES	YES	Not Required	Not Required	CONFORM	Requirements to be met according to EN 10993
Filter Penetration of Sodium Chloride (% Max)	Not Required	Not Required	Not Required	6	1	1.12	Requirements to be met according to EN 149:2001+A1:2009
Filter Penetration of Paraffin Oil (% Max)	Not Required	Not Required	Not Required	6	1	4.39	Requirements to be met according to EN 149:2001+A1:2009
Resistance to Breathing 30l/min	Not Required	Not Required	Not Required	≤ 0.7 mbar	≤ 1.0 mbar	0.10 mbar	Requirements to be met according to EN 149:2001+A1:2009
Resistance to Breathing 95l/min	Not Required	Not Required	Not Required	≤ 2.4 mbar	≤ 3.0 mbar	0.96 mbar	Requirements to be met according to EN 149:2001+A1:2009
Content CO2 of inhaled air (Max 1%)	Not Required	Not Required	Not Required	1.0	1.0	0.64	Requirements to be met according to EN 149:2001+A1:2009
Walking Test - Walk 10 min at a speed of 6 km/h	Not Required	Not Required	Not Required	YES	YES	CONFORM	Requirements to be met according to EN 149:2001+A1:2009
Working Simulation Test - Walk/Crawling/Filling	Not Required	Not Required	Not Required	YES	YES	CONFORM	Requirements to be met according to EN 149:2001+A1:2009
Oxygen Saturation (blood) Test reduction after 2 hours of Surgery Practice (SpO2 %)	Not Required	Not Required	Not Required	Not Required	Not Required	97*	*SpO2 pre-operative 99% - SpO2 post-operative 97%
Sterilizable in Autoclave	NO	NO	NO	NO	NO	YES*	*Sterilizable at 121°C - 8 Min up to 20 times
Sterilizable in Microwave Oven	NO	NO	NO	NO	NO	YES*	*Sterilizable at 700W - 1 min
Washable	NO	NO	NO	NO	NO	YES*	*Washable at 40°C - 30 min up to 5 times
Packaging (standard, may vary from brand)	Box 50 pcs unsealed	Box 50 pcs unsealed	Box 50 pcs unsealed	Box 5-10 pcs unsealed	Box 3-5 pcs unsealed	Box with 1 mask in thermosealed bag, packaged in medical level clean area	Requirements to be met according to EN 10993
Special hazardous waste volume	MIN 3 PCS PER DAY	MIN 3 PCS PER DAY	MIN 3 PCS PER DAY	1 PC PER DAY	1 PC PER DAY	1 PC PER 20 WORKING DAYS (waste reduction of 2000%)	Based on WHO and ISS indications of use
Production location (main export Countries)	China-Egypt-India	China-Egypt-India	China-Egypt-India	China	China-Europe-USA	ITALY*	*Manufactured in Italy by Axelmed with TNT of PP made in Germany
Average Price in EU applied to Professionals from Distributors	0,90 €	1,20 €	1,50 €	2,50 €	4,00 €	1,19 €	Price per day of use - Surgical Masks price is for 3 pcs per Working Day (min)
Price applied to Health Government Procurement Agencies (MoH) during the COVID-19 Emergency	0,30 €	0,45 €	0,60 €	1,40 €	2,20 €	0,64 €	Price per day of use - Surgical Masks price is for 3 pcs per Working Day (min)