INSTRUCTIONS FOR USE

MEDICAL FACE MASK CLASS I TYPE IIR

MODEL: **ALIVE PPE 9030**

PURPOSE: Alive PPE medical face mask is designed to limit the transmission of infection factors from staff to patients and from patients to staff in different environments. (according to EN 14683:2019+AC:2019 Medical Face Masks – Requirements and test methods)
It is approved that the product fulfils all essential requirements and related rules of 93/42/EEC Medical Devices Directive (MDD) Class 1 are applied.

Medical face masks are made with;

-outer layer is spunbond polypropylene 25 g/m^2 (+- 2 gr)

-middle layer is meltblown polypropylene 25 g/m^2 (+- 2 gr)

-inner layer is spunbond polypropylene 28 g/m^2 (+- 2 gr)

PROPERTIES:

Nose Bridge Wire: PE plastic covered wire

Elastic band: PES with EA band (Ear band)

Corner Band: Spunbond polypropylene 20 g/m^2

Fabric: SMS Fabric

LIMITATIONS:

Exposure to certain Chemicals or high concentrations may require higher protective properties through the material or construction properties of the face mask. The user will be the only one to assess compliance with the required type of protection and proper connection of the face mask with additional protective equipment.

METHOD OF USING FACE MASKS:

Before use, check that the selected product is suitable for the existing hazard.
Remove the face masks from the packaging.
Check visually that the face mask is intact (no piercing, no opening, no torn, no rupture, etc.)
Take the mask from package, put the elastic bands on your ears, covering the mouth and nose. Adjust the nose bridge wire for your nose.

WARNINGS:

*Care should be taken when removing contaminated face masks, so as not to contaminate the user with any hazardous substances. If face masks are contaminated then decontamination procedures should be followed (i.e. decontamination shower) prior to the removal of the face masks. This face mask is not designed for use in extreme environments.

*The determination of suitability of NARKONTEKS products for an application is the final responsibility of the user. This product is recommended for single use application. Upon contamination wear are damage the garment should be removed and appropriately disposed of at the earliest convenience.

*Where NARKONTEKS products are used in conjuction with other PPE, and for full "Type" protection it is necessary to tape cuffs to gloves, ankles to boots, the hood to the respiratory device. The user shall be the sole judge for the correct combination of NARKONTEKS garment and additional PPE.

TRANSPORT, STORAGE AND DISPOSAL:

The product must be transported and stored in the original packaging in dry rooms away from sources of light and heat. If the face masks are not contaminated, they can be disposed of with solid municipal waste. If they have been contaminated, they must be disposed of in accordance with applicable lawsand regulations.

USETIME:

İt is suggested to use the product within a period of five years from the date of production written on label
Month and year of production: MM/YYYY

EU ATTESTATION OF CONFORMITY

The information on the packaging for the above listed product covers the necessary information stated in Annex I, §23, of the Medical Device Regulation (EU) 2017/745. This information includes; reference to EN 14683 standard, type of mask (as indicated in table I) and other relevant information given in EN ISO 15223-1:2016 and EN 1041:2008+A1:2013. It's considered to be suitable to attach a CE mark, as seen below, on products in accordance with the information given in this certificate with publishing an EU Declaration of Conformity.

CONFORMITY WITH STANDARDS

EN 14683:2019+AC2019	Medical face masks- Requirements and test methods.	Type IIR	Result
EN 14683 – Annex B	Bacterial filtration efficiency	≥98	>99,9
EN ISO 11737-1:2018	Microbial cleanliness (Bioburden)	≤30	15,6
EN 14683 – Annex C	Differential pressure	<60	25,6
ISO 22609	Splash resistance pressure	≥16	26,3

DIMENSIONS OF PRODUCT

Length	174,0 mm
Width	96,0 mm
Nose Bridge Wire Lenght	(Min.) 95,0 mm
Elastic Band Length	About 140 mm or 180 mm

Parameters	Unit	Finding	Tip I	Tip II	Tip IIR	LR Source	Method	Information
Analyzed Mask Surface	-	Outside	-	-	-	-	-	
Point of Analysis	-	Midpoint	-	-	-	-	-	
Bacterial Filtration Efficiency								
BFE - 1	%	>99,9	≥95	≥98	≥98	97	EN 14683 - Annex B	122, 124, 129
BFE - 2	%	>99,9	≥95	≥98	≥98	97	EN 14683 - Annex B	122, 124, 129
BFE - 3	%	>99,9	≥95	≥98	≥98	97	EN 14683 - Annex B	122, 124, 129
BFE - 4	%	>99,9	≥95	≥98	≥98	97	EN 14683 - Annex B	122, 124, 129
BFE - 5	%	>99,9	≥95	≥98	≥98	97	EN 14683 - Annex B	122, 124, 129
Mean Positive Control Count	cfu	1835	-	-	-	-	EN 14683 - Annex B	
Negative Control Count	cfu	<1	-	-	-	-	EN 14683 - Annex B	
Mean Particle Size (MPS)	µm	3,2	-	-	-	-	EN 14683 - Annex B	
Microbial Limit - Bioburden								
Bioburden - 1	cfu/g	21	≤30	≤30	≤30	97	ISO 11737-1	120, 131
Bioburden - 2	cfu/g	12	≤30	≤30	≤30	97	ISO 11737-1	120, 131
Bioburden - 3	cfu/g	18	≤30	≤30	≤30	97	ISO 11737-1	120, 131
Bioburden - 4	cfu/g	16	≤30	≤30	≤30	97	ISO 11737-1	120, 131
Bioburden - 5	cfu/g	11	≤30	≤30	≤30	97	ISO 11737-1	120, 131

Parameters	Unit	Finding	Tip I	Tip II	Tip IIR	LR Source	Method	Information
Differential Pressure								
DP - 1	Pa/cm²	24,6	< 40	< 40	< 60	97	EN 14683 - Annex C	122, 123, 126, 144
DP - 2	Pa/cm²	29,5	< 40	< 40	< 60	97	EN 14683 - Annex C	122, 123, 126, 144
DP - 3	Pa/cm²	23,5	< 40	< 40	< 60	97	EN 14683 - Annex C	122, 123, 126, 144
DP - 4	Pa/cm²	25,2	< 40	< 40	< 60	97	EN 14683 - Annex C	122, 123, 126, 144
DP - 5	Pa/cm²	25,3	< 40	< 40	< 60	97	EN 14683 - Annex C	122, 123, 126, 144
Splash Resistance Pressure								
Splash Resistance Pressure	kPa	16	-	-	≥16	97	ISO 22609	122, 142, 146, 147
Number of Masks Analyzed	-	32	-	-	-	-	-	
Number of Passed Masks Analyzed	-	31	-	-	-	-	-	

PRODUCT LABEL (EXAMPLE):

Producer: NARKONTEKS
TEKSTİL İHR.İTH.SAN. VE TİC.A.Ş.
Dogus Cd, 3/19 Sk, No:12, Begos 35160,
Buca/IZMIR/TURKEY - 0090-232-4408686

Style Code: ALIVE PPE 9030
Class I Type IIR

MAINTENANCE AND CLEANING:

CE

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