



# INSTRUCTIONS FOR USE

DISPOSABLE DOUBLE SET, CLASS I

MODEL: ALIVE PPE 9063

**PURPOSE:** Alive PPE Disposable Double Set is a protective clothing with limited life, Class 1 protection

Disposable Double Set manufactured and designed for use to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures.

It is approved that the product fulfills all essential requirements and related rules of 9342/EEC Medical Devices Directive (MDD) Class 1 are applied.

### PROPERTIES:

Piping: SMS Nonwoven Poliproblen 40gr/m2  
Pocket: SMS Nonwoven Poliproblen 40gr/m2  
Tape: 3cm Knitted Elastane Tape  
Fabric: SMS Nonwoven Poliproblen 40gr/m2

### LIMITATIONS:

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

### METHOD OF PUTTING ON AND USING THE NON-STERIL DISPOSABLE DOUBLE SET:

Before use, check that the selected product is suitable for the existing hazard and in the correct size.

Remove the disposable double set from the packaging.

Check visually that the disposable double set is intact (no piercing, no torn seams, etc.)

Wear the upper garment first, then the lower garment without touching anything.

### CONFORMITY WITH STANDARDS

EN 13795-1 : 2019	Surgical clothing and drapes – Requirements and tests
EN ISO 11737-1:2018	Microbial Cleanliness
BS EN 22610:2006 1:2018	Test method for determination of resistance to wet bacterial permeability
ISO 22612: 2005	Test method for resistance to dry microbial penetration
EN 29073-3:1196 (*)	Tensile Strength Wet & Dry
ISO 13938-1: 1999	Bursting Strength Wet & Dry

### SIZES AND DIMENSIONS OF BODY (CM) –

	ONE SIZE
Fr.Length from HPS	77 cm
Sleeve Length	31 cm
1 / 2 Bottom Hem	57 cm
Pocket length (tshirt)	16 cm
Pocket width (tshirt)	14 cm
1 / 2 waist width	34 cm
pants all length (including belt)	105 cm
1 / 2 cuff width	24 cm
BELT HEIGHT	3 cm
Pocket length (pants)	21 cm
Pocket width (pants)	18 cm

### PRODUCT LABEL (EXAMPLE):

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

Style Code: ALIVE PPE 9063  
Disposable Double Set Class I



### MAINTENANCE AND CLEANING:



One Size



### WARNINGS:

The Disposable Double Set is intended for single use and should be discarded after use Accepted configuration cannot be modified or changed.

If tears, punctures etc. occur, immediately leave the workplace and put on a new Disposable Double Set Do not remove the Disposable Double Set if the user is still in the danger area Disposable Double Set with electrostatic properties must not be opened or removed when in a potentially explosive or flammable atmosphere or carrying explosive, flammable substances.

To provide complete protection, all openings should be closed/sealed.

Extended wearing of Disposable Double Set can cause heat stress.

Overheating and discomfort can be reduced or eliminated by using appropriate undergarments or appropriate ventilation equipment.

The product is flammable - keep away from fire.

### 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 suits 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 laws and regulations.

### USE TIME:

It 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

PROPERTIES	TEST METHOD	UNIT	TARGET
WEIGHT	NWSP 130.1.R0 (15)	gsm	40
THICKNESS	NWSP 120.1.R0 (15)	mm	0,37
TENSILE STRENGTH	MD	N/5 cm	108,5
	CD		49,5
ELONGATION AT BREAK	MD	%	135,5
	CD		119,5
HYDROSTATIC HEAD	NWSP 080.6.R0(15)	mm	400,0
<b>Tolerances For The Average Results</b>			
Weight	± 5 %	<b>Roll Tolerance</b> <b>Length</b> : - 0 / +5% against target / ordered length <b>Width</b> : Up to 150 cm in width – 0mm/+5mm Over 150 cm in width – - 0mm/+10 <b>Splice</b> : Maximum five splices per roll	
Thickness	± 10 %		
Tensile Strength	± 15 %		
Elongation	± 15 %		
Hydrostatic Head	± 15 %		
Liquid Strike-Through Time	± 0,5 %		
Air Permeability	± 20 %		
Absorption	± 20 %		
The product is wound onto cardboard cores and then wrapped in polyethylene film. Bar code labels with product code, description and lot details are applied to the outside of each pack and a small label is applied to each roll. Suitable sized rolls may be palletised and the pallet load cling-wrapped			
Preparation Date	QUALITY CONTROL APPROVAL		
23.06.2020			

### EU DECLARATION OF CONFORMITY:

European Regulation(EU) 2017/745 and 93/42/EEC Medical Devices Directive establishing technical requirements for medical devices , in effective wording