



INSTRUCTIONS FOR USE

SURGICAL GOWN , CLASS I

MODEL: ALIVE PPE 9060

PURPOSE: Alive PPE one-piece surgical gown is a protective clothing with limited life, Class 1 protection (according to EN 13795-1: 2019)

Surgical gowns 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 fulfils all essential requirements and related rules of 9342/EEC Medical Devices Directive (MDD) Class 1 are applied.

PROPERTIES:

Cuff: Knitted Elastics
Neck Closure: Velcro neck closure for better adjustments to several people.
Belts: 2 ties system for outside.
Fabric: Endless Filaments Meltbown Thermally Bonded. 100% PP SMS Hydrophobic fabric 40 g / m²,

LIMITATIONS:

Exposure to certain Chemicals or high concentrations may require higher protective properties through the material or construction properties of the surgical gown. 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 SURGICAL GOWN:

Before use, check that the selected product is suitable for the existing hazard and in the correct size.
Remove the gown from the packaging.
Check visually that the isolation gown is intact (no piercing, no torn seams, etc.)
Wear first on sleeves, close/adjust the velcro on back neck, tie the back belts.

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) –

	L	XL
Fr.Length from HPS	115,0	117,0
1 / 2 Bottom Hem	75,0	79,0
Sleeve Length	56,5	57,5
Cuff	6,0	6,0

PRODUCT LABEL (EXAMPLE):

Producer: **NORKONTEKS**
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 9060
Surgical Gown Class I



MAINTENANCE AND CLEANING:



WARNINGS:

The surgical gown 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 gown Do not remove the gown if the user is still in the danger area
Surgical gown 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 surgical gown 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

Tolerances For The Average Results

Weight	± 5 %	Roll Tolerance Length : - 0 / +5% against target / ordered length Width : Up to 150 cm in width – 0mm/+5mm Over 150 cm in width – - 0mm/+10 Splice : 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 polyethylen 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

Technical standard EN 13795-1:2019 Surgical clothing and drapes – Requirements and test methods – Part 1: Surgical drapes and gowns



L



XL