

# LEVEL 3 ISOLATION GOWN AAMI PB70

# **TECHNICAL DATA SHEET**

## **DGown DG12 Surgical/Isolation Gown**

Surgical/Isolation Gown is fully compliant with EN 13795-1 standards. It is made from a Non-woven SMMS, SSMMS fabric with PE reinforced providing AAMI level III protection. It offers exceptional protection against fluids under moderate or high liquid pressure conditions.

#### **KEY FEATURES**

- •Complies with EN 13795-1:2019.
- •These gowns are for single-use.
- Side ties eliminate difficulties of tying behind the back.
- Velcro closure on the neck provide a generous size for full coverage and flexibility.
- •They include functional cuffs constructed of a white knitted material.
- Provided latex-free.
- •This Gowns are Non-Sterile.
- Knitted cuffs provide a soft wrist closure for increased comfort.
- PE reinforcement applied on critical zones for extra protection.
- •Offers protection against biohazards.

## **APPROVALS**

Fulfill the requirements for Class I MDR under Medical Device Regulation (EU) 2017/745. These gowns also fulfill all essential requirements and the related rules of the European Economic Commission 93/42/EEC Medical Devices Directives (MDD). They also comply with AAMI Protective Barriers classification system and the associated minimum requirements for the liquid barrier performance of protective appparel and drapes based on ANSI standards.



#### **SIZING**

An appropriate size garment should be selected to allow sufficient movement for the task whilst maintaining a secure fit.



SIZE CHART		
SIZE	HEIGHT	CHEST
s	112 cm	61 cm
М	115 cm	62,5 cm
L	123 cm	66 cm
XL	135 cm	69,5 cm
XXL	148 cm	73 cm
3XL	158 cm	76 cm

#### **MATERIALS**

SUIT	Non-woven SMMS+PE	
WEIGHT	55-65 gr/m2	

#### STORAGE AND DISPOSAL

- •Store in dry, clean conditions in original packaging, away from direct sunlight, sources of high temperature, and solvent vapours.
- •Expected shelf life is five years from the date of manufacture when stored as stated.
- •Replace garment if damaged, heavily contaminated or in accordance with local work practice or regulations.
- Handle and dispose of contaminated garments with care and in accordance with applicable regulations.

#### WARNING AND LIMITATIONS

Make sure that product is suitable for the application and fitted correctly. Product must never be altered or modified. Final determination as to

the suitability of these product for a particular situation is the employer's responsibility. This information is subject to revision at any time.

## LIMITED USE









Single use

Do not wash

Do not bleach

Do not iron



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o not

Flammable

## **INTENDED USE**

- For use in clinical and surgical (if sterile) operations.
- •Intended to protect from the transfer of microorganisms and bodily fluids in moderate or high risk patient surgical situations.
- •Typical applications may include blood, bodily fluids and environmentally controlled cleanroom applications.

#### **PACKAGING**

Each gown is individually folded and packaged into a bag