

## TECHNICAL DATASHEET FOR REINFORCED SURGICAL GOWNS

### Designation

Disposable Reinforced Surgical Gown

### Description

Reinforced surgical gown available with selection between different materials and sizes.

### Usage

Reinforced Surgical Gowns are used to reduce risk of infection and create a layer of protection against splash for surgeons in all kinds of operations. Critical parts are reinforced with an extra layer.

### Transport

Gowns are transported in a carton boxes. Basic warnings and information is printed on cartons with manufacturer information and contact details. CE marking and name of set can be seen on carton boxes.

Reference No	Carton Dimensions (W x D x H – mm)	Number of Sets / Carton
DG - 5003	600 x 400 x 350 mm	50

### Packing

All components are packed with pouch pack.

- Pouch Pack: Gown is packed in a sterilization pouch with size depending on the selection of dimension and type of folding requested. Pouch has necessary peeling opening available.

Packages show the information below:

- Product series name & product name
- Set type (dimensions and type of drape)
- Set contents with quantities
- Manufacturing date
- Date of expiry
- Lot number
- Reference number
- Sterilization indicator
- Method of sterilization

- Warnings (don't use open packages, for single use only, latex free)
- Manufacturer contact & company information
- CE Label

## Sterility

Reinforced Surgical Gowns are sterilized with EO sterilizer in house. Sterilization is documented and monitored through necessary forms, biological indicators, chemical indicators, dosimeters and data loggers.

It is possible to have NON-STERILE products upon request with same variety of selections from sizes and materials available.

## Shelf Life

Product has been tested for stability. Test reports show that Reinforced Surgical Gowns have a shelf life of 3 years.

## Quality Certification & Compliance

All process across ADEN MEDICAL is run in compliance with EN ISO 9001 & EN ISO 13485.

Independent third party laboratories tested for packing sealing strength is in compliance with EN ISO 868-5, stability according to ASTM F 1980 and package leak tests according to ASTM F 1929. Thermoforming line is validated for temperature and pressure settings according to EN ISO 17025.

Sterilization process has been validated according to EN ISO 11135-1, for sterilization by Ethylene Oxide. Sterilizer is also validated by IQ and OQ tests.

Our manufacturing plant and clean room is in compliance and been tested for EN ISO 11605, EN ISO 14644-1, EN ISO 14644-2, EN ISO 14698-1 and EN ISO 14698-2 tests for bio contamination levels in order to assure relevant safety levels in all products.

Reinforced surgical gowns are tested for bio-burden according to EN ISO 11737-1. To achieve highest quality EO residue is also tested according to EN ISO 10993-7.

Reinforced Surgical Gowns are CE Class IS products and have been certified by independent third parties from EU for compliance with standards.

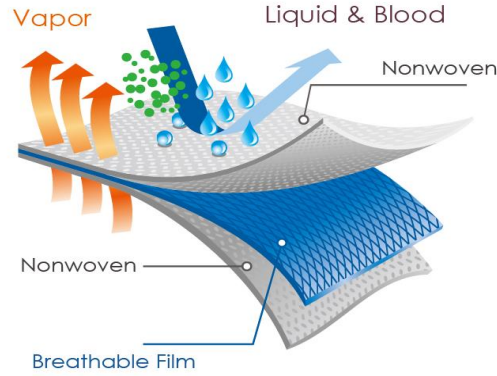
## Content

Description	Qty.
Reinforced Surgical Gown	1
Hand Towel, 40 x 40 cm.	1

## Materials of Selection

Reinforced Surgical Gowns are packed in sterile packages. All Reinforced Surgical Gowns can be made of from one of the below listed selections for gown:

- SFS (65 gr/m<sup>2</sup>)



All Reinforced Surgical Gowns have Velcro on backside of neck section. Waists are as soft knitted cuff.

. Hand towels in packages can be made of from one of the below listed selections for gown:

- Cellulose - PE (54 gr/m<sup>2</sup>)

Hand towels in packages can be sized from one of the below listed selections for gown:

- 40 x 40 cm.
- No towel!

## Available Dimensions

All Standard Surgical Gowns are available in:

XS (length 105 cm. front 140cm, 5%, sleeve length: 50 cm ±5%),

S (length 110 cm. ±5%, front 140 cm, sleeve length: 50 cm ±5%),

M (length 117,5 cm. front 145cm, ±5%, sleeve length: 50 cm ±5%),

L (length 125 cm. ±5%, front 150 cm, sleeve length: 50 cm ±5%),

XL (length 132,5 cm. ±5%, front 150 cm, sleeve length: 55 cm ±5%),

XXL (length 140 cm. front 155 cm,  $\pm 5\%$ , sleeve length: 60 cm  $\pm 5\%$ )

XXXL (length 150 cm.  $\pm 5\%$ , front 155 cm, sleeve length: 60 cm  $\pm 5\%$ ) sizes.

It is possible to have different dimensions for certain quantities. Please request information from your Agent / Sales Representative.

### Storage

Store the product under normal conditions for healthcare material, in a cool and dry place protected from light. The use of medical grade paper and film guarantees its sterility for the duration of its shelf life under normal transport and storage conditions.

### Comments

The product must be used by specialized personnel only. Check the package's integrity before use. Do not use if the package is open or damaged.