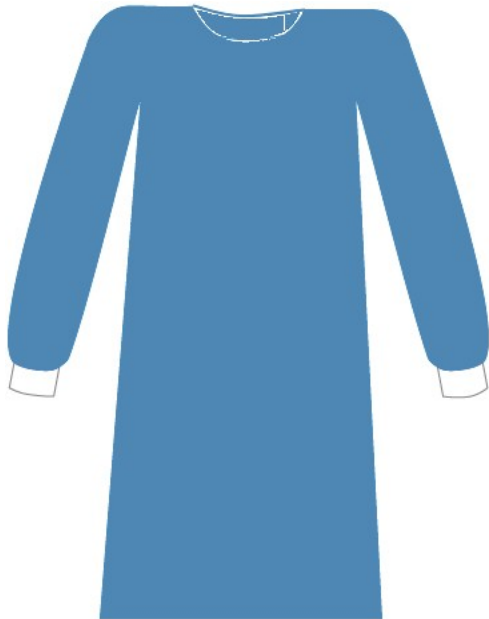


Standard surgical gown, spunlace blue



Premium raw material for **extra comfort**

Alcohol repellent and anti-static treatment raw material for superior barrier effect.

Low fiber release which reduces the risk of contamination. Low linting and with absorbent strong towels.

Designed and produced in accordance with **Directive 93/42/EEC**, revision **2007/47/CE** and **EN 13795**, this medical device provides an effective barrier on the prevention and/or control of infectious agents transmission in **procedures with low/medium level of liquids**.

Two detachable labels in the primary package for **full traceability**.

Reference	Size	Color	Unit per box
GOW.2020	M	blue	30 un
GOW.2030	L	blue	30 un
GOW.2040	XL	blue	28 un
GOW.2045	XL-XL	Blue	24 un
GOW.2050	XXL	blue	26 un

Intended of use:

The medical devices in this subcategory are intended to prevent the transmission of infectious agents between patients and clinical staff during both invasive and non-invasive surgical procedures. Therefore, the intended users of these medical devices are healthcare professionals and the patient population are people undergoing surgical procedures.

Suitable for surgical procedures that provides low/medium quantity of liquid.

Product description:

Sterile standard surgical gowns, for a single use.

Surgical gown available in different sizes, wrapped in a medical paper, with 2 hand towels of 43x30 cm in 100% cellulose with high absorbency in a single sterile package.

Product develop for a standard performance.

Raw materials:

Basic raw material is spunlace 68g/m² (cellulose 55%/polyester 45%), with anti-static treatment and alcohol repellent treatment.

Low release of fibers, repellent to liquids and with high resistance to traction and bursting, permeable to air and with low flammability.

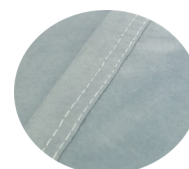
Materials used are latex free.

Design and construction:

Ergonomic design provides greater freedom of movement to the user without compromising the safety or quality.

Backs of the gown overlapped to maintain the sterility on both the front and back of the user. Long sleeve that prevents sliding of the surgical glove during the procedure. 100% Polyester, anti-allergic cuffs with Oeko-Tex[®] Standard 100 certified. Adjustable velcro collar, 4 belts and 1 transfer card allow a perfect adjustment to the user and an application of the recommended aseptic technique.

Sewn seams with two needle with an overlapping edge for barrier effect.



Folding:

It's presented with functional fold that allows maintaining asepsis when correctly used by the medical staff during manipulation of sterile product.

Gowns are wrapped in medical crepe paper with 55x55 cm and 45g/m².
Final fold dimension: 16x24 cm



Packaging:

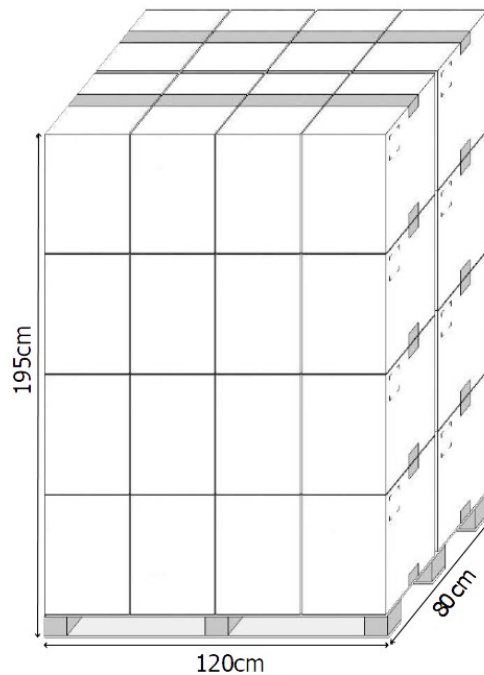
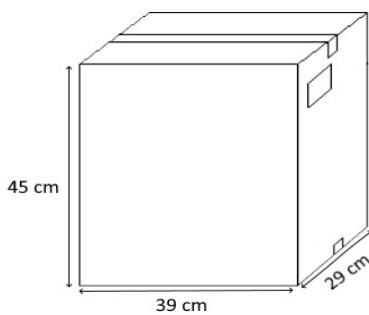
Single multivac package, with two detachable labels in the primary package for full traceability.

Double packaging system with carton and polyethylene bag for added protection against dust, moisture and transport damage, handling and storage.



Outer box (39x29x45 cm)

Palletizing system: 32 boxes per pallet: 1.20x0.80x1.95 cm.



Labelling:

The product is identified with a label indicating size, image, performance and product description, as well as harmonized regulations according to applicable standards.

Contains two easily to removable traceability labels that contain product reference, expiration, lot and bath information.

Identification label in outer carton.

Sterilization:

Product sterilized by ethylene oxide.
According to applicable standards.

Shelf Life:

5 years if storage on the correct way.
Product should be protected from sunlight and kept dry.

Directive:

Medical device: Class I sterile, rule 1.

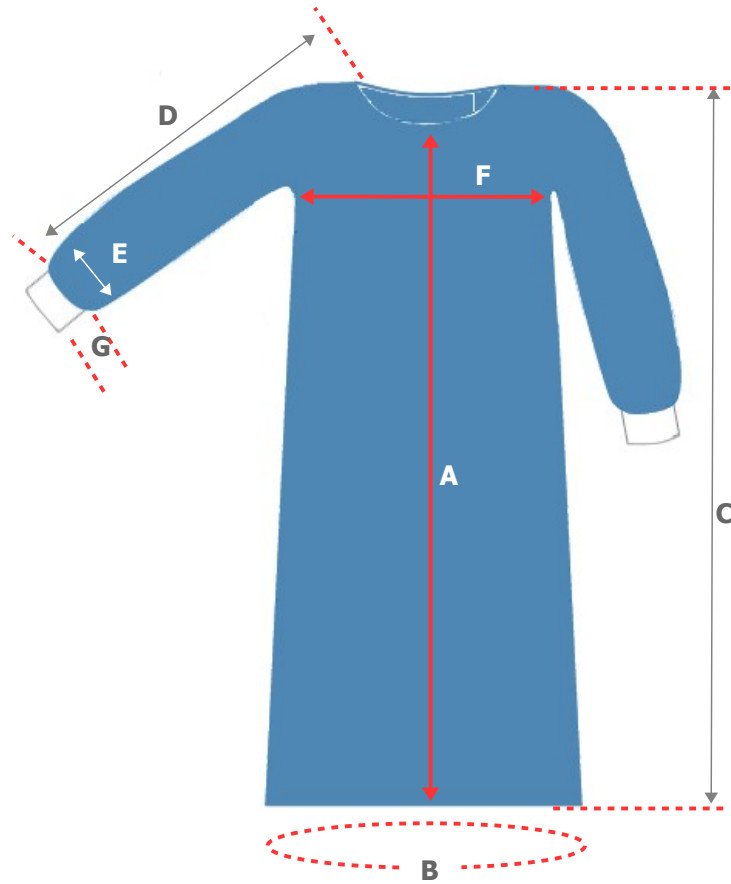
Product in compliance with the Essential Requirements of Directive 93/42 / EEC as amended by Directive 2007/47 / EC and applicable standards

Applicable Standards:

EN ISO 20417, EN ISO 11135, EN ISO 11607, EN ISO 11737, EN ISO 13485, EN 13795-1, EN ISO 14971, EN ISO 15223-1, EN 556-1, EN ISO 10993-1, EN ISO 10993-5, IEC 62366-1, EN ISO 10993-7, EN ISO 10993-10, ISO 14698-1

Measures:

1. General dimension of gowns:



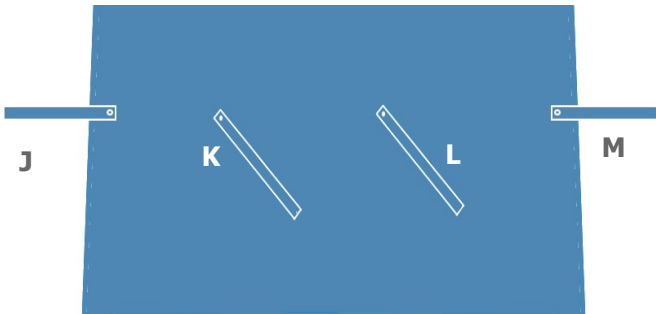
(all measure in cm)	M	L	XL	XL - XL	XXL	Tol
A = Front length	111	121	130	153	141	+/- 2
B = Circumference	146	156	157	160	172	+/- 3
C = Heighest point	120	130	140	164	152	+/- 2
D = Length of the sleeve without cuff	72	76	82	85	85	+/- 2
E = Width of sleeve 5 cm from the union of the wrist	16	16	16	16	16	+/- 2
F = Chest	66	70	76	76	82	+/- 3
G = Length of cuffs	7,5	7,5	7,5	7,5	7,5	+/- 1,5

2. Velcro:



(all measure in cm)	M	L	XL	XL-XL	XXL
H = Loop fastener	9,5x3				
I = Hook fastener	5x3				

3. Belt dimension:



(all measure in cm)	M	L	XL	XL-XL	XXL
J = Outer	62 x 3,8				
K = Inner	44 x 3,8				
L = Outer	44 x 3,8				
M = Outer	44 x 3,8				

Transfer card on belts **J** and **L** allows safe handling

