

# Technical Data Sheet

## Non-woven medical gown



### PRODUCT DESCRIPTION

Type of the product	Non-woven medical gown made of non-woven Spunbond fabric, tied at the back and at the neck with ties. Sleeves finished with elastic band. Standard sewing and folding method. Non-sterile product, for single use.	
Intended use	A non-woven medical gown creates a barrier that minimizes the direct transfer of infectious agents and bacteria to the surgical wound, which limits the possibility of wound infection and reduces the risk of post-operative complications, or generally reduces the possibility of transfer of pathogenic microorganisms during procedures. A non-woven medical gown is a barrier medical device designed to provide a clean barrier, when there is no need to use sterile surgical gowns - in emergency departments, hospital emergency departments, surgical departments, and during minor surgical procedures. The device can also be used in other clinical hazardous environments, such as emergency rooms, delivery areas and intensive care units, or in the care of immunocompromised patients. For use by qualified personnel (professional users). Single-use product, non sterile.	
Material	Gown	Polypropylene non-woven type Spunbond
Elastic type	latex free	
Weight	24 g/m <sup>2</sup>	
Colour	blue / green	
Size	M / L / XL / XXL	
Packaging	10 pcs / polybag; 10 x 10 pcs / carton	

### PRODUCT REFERENCES

Size / Colour / Reference Number		Blue	Green
	M	W267100230_0028	W267200230_0028
	L	W267100240_0028	W267200240_0028
	XL	W267100250_0028	W267200250_0028
	XXL	W267100260_0028	W267200260_0028

### PHYSICAL PROPERTIES

Dimensions		M	L	XL	XXL	Tolerance [cm]
	Length of the gown [cm]	120	124	128	132	± 2
	Width of the gown [cm]	140	146	150	156	± 2
	Length of the sleeve [cm]	60	62	64	66	± 2
	Armhole [cm]	26	27	28	29	± 2
	Length of each neck tie [cm]	33	33	33	33	± 5
	Total length of the waist tie [cm]	164	164	164	164	± 10

### MANUFACTURING AND SAFETY STANDARDS

Classification	<b>Medical Device: CE</b> Class I (Regulation (EU) 2017/745)
Compliance with product standards	EN ISO 15223-1, EN ISO 20417, ISO 10993-1, ISO 10993-5, ISO 10993-10, EN ISO 14971
Compliance with quality standards	EN ISO 13485, ISO 9001, ISO 14001, ISO 45001

REACH

Product does not contain any of the chemicals listed in the REACH “Candidate List of Substances of Very High Concern” according to REACH Regulation (EC) No 1970/2006.

STORAGE AND DISPOSAL

Storage instruction

It is recommended to store product in dry place, in temperature of 5-30°C and to protect them against direct sunlight. Keep product in a distance of not less than 1m from heating devices, sources of fire and ozone. Do not keep in direct vicinity of solvents, oils, fuels and lubricants.

Transport instruction

Transport in conditions ensuring an appropriate hygienic standard, protecting product against dirt. The product is not thermolabile - changing conditions regarding temperature or humidity in the short-term transport period do not affect the usability of the product or its properties or safety of use in any way. The product does not require transport in controlled conditions in terms of temperature and humidity (confirmed on the basis of accelerated aging tests and risk analysis).

Shelf life

5 years

Product disposal

If product has been used and has come into contact with body fluids or infectious substances, product should be disposed of as a contaminated product.

Packaging disposal

Foil packaging made of homogeneous material, does not contain different types of materials, does not require separation into fractions. The packaging is 100% recyclable, in accordance with local regulations.

Transport carton disposal

Transport carton packaging made of homogeneous material, does not contain different types of materials, does not require separation into fractions. The packaging is 100% recyclable, in accordance with local regulations.