# AMBULANZKITTEL

**REF 627130 (as of LOT 136594)**

## Product Description, Intended Use, Application

The protection gown, **size XXXL**, is made of nonwoven and is fluid-resistant. The gown is open at the back, with elastic knitted cuffs, waist, and collar ties. The cuffs allow for a tight fit of disposable gloves. Due to the breathable and soft material, the product is comfortable to wear. The blue colour of the protection gown can be used for the purpose of assigning areas, e.g., for the care of intensive care patients. The use of the gown reduces the spread of contaminations during nursing or medical activities, especially for non-inpatient facilities, emergency rooms and intensive care units. The gown is intended for single use.

## Composition

Polypropylene
Cuffs: polyester

## Contraindications

The product should not be used in the case of a known allergy against the material.

## Incident reporting

According to MDR (EU) 2017/745, if serious incidents occur in relation to the device, they must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

## Normative and Regulative Requirements, Common Standards

Medical Device according to MDR (EU) 2017/745.

The gown passed the liquid penetration tests according to ANSI/ AAMI PB70:2012 standard for level 3 (AAMI level 3 medium liquid protection).

The product does not contain dangerous toxic substances according to REACH.

## Packaging

Primary packaging:     PE- bag

Secondary packaging:  carton
                       made of cellulose

## Symbols used in labelling

Explanations at www.nobamed.com

Marking on all packaging levels with CE and according to DIN EN ISO 15223-1- and DIN EN ISO 20417

## Storage and Transport

Dry and dustfree.

## Single use device

Reusing aa single use medical device can lead to microbiological danger. Reprocessing, for reuse can decrease the product's performance significantly.

## Disposal

According to locally applicable legal regulations and standards of infection prophylaxis.