



## NOBAVEK®

### Product Description and Purpose

Disposable overall for the protection of patients and users against infective agents, with elastic cuffs, hood and zipper in the front, but without shoes. Because of its soft material the overall is comfortable to wear. It is liquid-tight, abrasion-proof and low-particle. NOBAVEK® protects the patient against a contamination by the person wearing the disposable overall. At the same time the probability is reduced for the wearer of getting into touch with airborne microorganisms, blood or body fluids.

### Composition

Polypropylene

### Packaging

Primary packaging: PP bag

Secondary packaging: carton made of cellulose

### Storage

To be stored in a dry and dust-free environment

### Normative and Legal Requirements

NOBAVEK® is a medical product in accordance with the MDD, class I, rule 1, and complies with the requirements of the directive 93/42/EEC and of following standards concerning to PPE:

**EN 1149-1** Protective clothing—Electrostatic properties — Part 1: Surface resistivity (test methods and requirements) at 25 % air humidity:  $5.5 \times 10^{13} \Omega$

**DIN EN ISO 10993** Series of standards "Biological evaluation of medical devices": The product did not show any indication of irritation, sensitization or cytotoxicity.

**DIN EN ISO 14126** Protective clothing – Performance requirements and test methods for protective clothing against infective agents

**ISO 16603** Resistance to penetration by blood and body fluids-synthetic blood, together with

**ISO 16604** Resistance to penetration by bloodborne viruses using the bacteriophage Phi-X174: passed with 14 kPa class 5 of 6

**ISO 22610** Resistance to penetration by bacteria-mechanical contact with fluids: breakthrough time: > 75 minutes class 6 of 6

**ISO/DIS 22611** Resistance to penetration by biologically contaminated aerosols: Log R >5 class 3 of 3

**ISO 22612** Resistance to penetration by contaminated dust: Log cfu <1 class 3 of 3

The product does not contain dangerous toxic substances according to REACH. It has CE marking and EN 980 labels on all its packaging.

