



**NOBAMED Paul Danz AG**

## NOBAFEEL®

**REF 910260**

### Product Description and Purpose

Very elastic and tearproof sterile disposable surgical gloves, **size 6**, made of latex. The synthetic internal coating allows easy and quick donning and reduces the risk of allergies, still backed by the fact that the gloves are powder-free. The surgical gloves are anatomically shaped, thus preventing symptoms of fatigue of the material, in particular during lengthy operations. The micro-rough surface of hand and fingers increases the grip reliability without reducing the tactile sensitivity. NOBAFEEL® gloves have rolled cuffs which considerably facilitate the donning.

### Recommendation for Use

The gloves are suitable for all surgical interventions.

### Contra-Indications

NOBAFEEL® gloves contain natural rubber latex that may cause allergic and anaphylactic reactions.

### Composition

Latex, polymer coating, ZDEC, ZDBC  
The accelerators and antioxidants used can hardly be verified within the gloves. No thiurames, toluenes or ureas are used.

### Normative and Legal Requirements

NOBAFEEL® gloves are a class IIa, rule 6, medical product according to the MDD, the directive 93/42/EEC and the MDR (EU) 2017/745. They comply with the requirements of the EN 455, parts 1, 2, 3, and 4., ASTM D 3577 and ISO 10282.

According to the European standard EN ISO 10993-1 "Biological Evaluation of Medical Devices", NOBAFEEL® gloves are medical devices with contact to body surfaces (injured or damaged skin) and with a contact time A (less than 24 h).

The AQL is 1.0 referring to the imperviousness, in compliance with the requirements of EN 455-1. The protein content

is  $\leq 50 \mu\text{g/g}$  (ascertained acc. to Lowry test 455-3) for all gloves. The powder content of all gloves is below the maximum allowable normative limit of 2 mg/ glove (DIN EN ISO 21171, ASTM D6124). The biocompatibility is tested in accordance with DIN EN ISO 10993, the virus imperviousness in accordance with ASTM F 1671-97b. The endotoxin value of less than 20 EU/ pair of gloves complies with the requirements of EN 455-3. The product's shelf life period is 5 years, verified according to EN 455-4.

Sterilization of the product complies with DIN EN 11135.

The product does not contain dangerous toxic substances according to REACH. It has DIN EN ISO 15223-1 and EN 1041- labels on all its packaging.

### Packaging

Primary packaging: paper wrap  
Secondary packaging: folding box made of cellulose  
Tertiary packaging: carton made of cellulose

### Storage

To be stored in a dry and dust-free environment, protected against direct sunlight, temperature must not fall below 5°C and not exceed 30°C.

The product bears the following marking and symbols.

