



## NOBAFEEL®

REF 910265

### Product Description, Intended use, Application

Very elastic and tearproof sterile disposable surgical gloves, **size 6.5**, 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. The worn glove provides a barrier against potentially infectious fluids and other contaminants.

### 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.

### Contraindications

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

### Recommendation for Use

The gloves are suitable for all surgical interventions.

### 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 MDD 93/42/EEC, 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.

The AQL is 0.65 referring to the imperviousness.

The virus imperviousness is tested in accordance with ASTM F 1671.

Sterilization of the product complies with DIN EN 11137.

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

### Packaging

Primary packaging: paper wrapping in film packaging

Secondary packaging: folding box made of Cellulose

Tertiary packaging: carton made of cellulose

### Symbols used in labelling

Explanations at [www.nobamed.com](http://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**

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.

### **Sterile device**

Before using a sterile product, visually inspect the packaging to ensure that it is intact.

### **Single use device**

Reusing a 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.