



NOBAFEEL®

Product Description and Purpose

Very elastic and highly tearproof sterile surgical gloves 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, in particular during lengthy operations. The microrough surface of hand and fingers increases the grip reliability without reducing the tactile sensibility. NOBAFEEL® gloves have rolled cuffs which facilitate the donning.

Composition

Latex, acrylic, ZDEC

The accelerators and antioxidants used do not exceed the admissible limits. No thiurames, toluenes or ureas are used.

Normative and Legal Requirements

NOBAFEEL® is a medical product in accordance with the MDD, class IIa, rule 6, and complies with the requirements of the directive 93/42/EEC and of the EN 455, parts I, II and III.

The **AQL** is ≤ 1.0 referring to the imperviousness. The **protein content** is $< 15 \mu\text{g/g}$ (ascertained acc. to mod. Lowry test, EN 455-3) and $< 10 \mu\text{g/g}$ (analysis of amino acid). The powder content is ascertained acc. to

DIN EN ISO 21171, ASTM D6124. The powder content of powder-free gloves is below 0.06 mg/glove. The maximum allowable normative limit is 2 mg/glove. The biocompatibility is tested in accordance with **DIN EN ISO 10993**, the virus imperviousness in accordance with **ASTM F1671-97b**. Sterilization of the product complies with DIN EN 11135.

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

Packaging

Primary packaging: paper packaging
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 exceed 30°C

