NOBAMED Paul Danz AG

NOBAFEEL®

REF 910280

Product Description and Purpose

Very elastic and tearproof sterile disposable surgical gloves, **size 8**, 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 ≤ 50 µg/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.

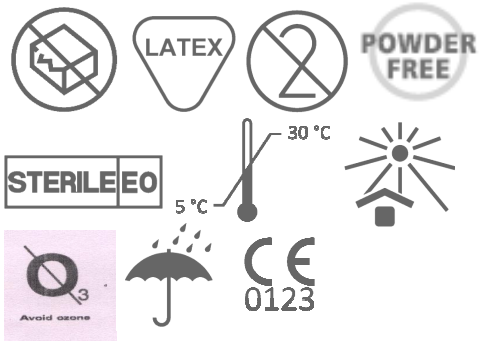
Packaging

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.



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