



NOBAMED Paul Danz AG

NOBAFEEL[®]-Syntex

REF 914280

Product Description, Intended use, Application

Very elastic and highly tearproof sterile disposable powder free surgical gloves, **size 8**, made of neoprene. The synthetic internal coating allows easy and quick donning. The surgical gloves are anatomically shaped, thus preventing symptoms of fatigue, in particular during lengthy operations. The micro-rough surface of hand and fingers increases the grip reliability without reducing the tactile sensitivity. NOBAFEEL[®]-Syntex gloves have rolled cuffs which considerably facilitate the donning. The gloves are lime green colored. The worn glove provides a barrier against potentially infectious fluids and other contaminants.

Composition

Neoprene, polyurethane polymer, ZDBC, DPG
The accelerators and antioxidants used do not exceed the admissible limits. No thiurames, toluenes or ureas are used.

Contraindications

The product should not be used in the case of a known allergy against the material.

Recommendation for Use

The gloves are suitable for all surgical interventions.

Note

Device is latex free.

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 Regulatory 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. and ISO 10282.

The AQL is 0.65 referring to the imperviousness.

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



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.