NOBAMED Paul Danz AG

NOBAFEEL®-Gyn

REF 913265

Product Description, Intended use, Application

Very elastic and highly tearproof sterile disposable surgical gloves, **size 6.5**, made of latex. The extra **length of 480 mm** protects the forearm against contamination specifically during gynaecological and obstetrical procedures. 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 micro-rough surface of hand and fingers increases the grip reliability without reducing the tactile sensitivity. NOBAFEEL®-Gyn 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 do not exceed the admissible limits. No thiurames, toluenes or ureas are used.

Contraindications

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

Recommendation for Use

The gloves are suitable for all gynaecological and obstetrical 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.

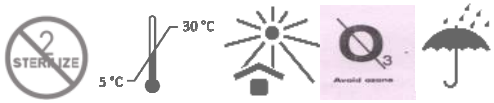
They comply with the requirements of the EN 455, parts 1, 2, 3, and 4., ASTM D 3577 and ISO 10282.
The AQL is 0.65 referring to the imperviousness.
The virus imperviousness is tested in accordance with ASTM F 1671.
Sterilization of the product complies with DIN EN 11137.
The product does not contain dangerous toxic substances according to REACH.

Packaging

Primary packaging:	paper wrap 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.