



MUNDPFLEGE-SET

REF 694520 (as of LOT 137715)

Product Description, Intended use, Application

The sterile oral hygiene pouch consists of
10 x loop gauze balls, Ø 3,0 cm
1 x universal clamp, shear-shaped, blue
1 x plastic tray with closing lid
1 x plastic cup

The gauze balls can be soaked with a suitable solution for oral hygiene. By means of the universal clamp the patient's oral cavity can be cleaned with the balls.

Composition

Loop gauze balls: cotton
Universal clamp: polystyrene
Plastic tray and cup: PET

Contraindications

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

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 MDR (EU) 2017/745.

Sterilization of the product complies with DIN EN ISO 11135.

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

Packaging:

Primary packaging: paper-film-packaging
Secondary packaging: PE-bag
Tertiary packaging: carton made of cellulose

Symbols used in labelling

Explanation 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

Dry and dustfree

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.