



## KRÜLLGAZETUPFER

REF 875420

### Product Description, intended use, application

The 1-ply darts are made of gauze (DIN EN 14079 type 20) and are used for the treatment of wounds and disinfection of the skin. Due to their longish shape, they are particularly suited for the application of ointments. If the darts are unfolded, they may also be used as a cover.

Prior to these activities, the product has to be sterilized with a validated procedure (moist heat at 121°C / 134°C, 2 to 3 bar, according to DIN EN ISO 17665, radiation according to DIN EN ISO 11137 or ethylene oxide according to DIN EN ISO 11135).

### Composition

Cotton

### Note

Sterilize before use

### 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 Legal Requirements

KRÜLLGAZETUPFER (gauze darts) is a medical product according to the directive 93/42/EEC and the regulation MDR (EU 2017/745).

The gauze complies with the requirements of DIN EN 14079 type 20.

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

### Packaging

Primary packaging: PE-bag

Secondary packaging: carton made of cellulose

### Symbols used in labelling

Explanations at [www.nobamed.com](http://www.nobamed.com)



Marking on all packaging levels with CE and according to DIN EN ISO 15223-1 and DIN EN 1041.

### Storage and Transport

Dry and dustfree

### 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.

### Storage

To be stored in a dry and dust-free environment