

NOBAMED Paul Danz AG

# HALSKRAWATTE

### REF: 373112

# Product Description, Intended use, Application

The cervical collar (12 cm, small neck circumference, 33 cm - 38 cm) has an anatomical fit and a convenient hook and loop fastener. The cover offers a good wearing comfort. The cervical collar is used to immobilize the cervical spine.

The bandage is, fasteners closed, washable at 30° C in the case of domestic use. Due to its material composition, the product may not be treated chemo-thermally and may therefore not be used on different patients.

#### Composition

Cotton, polyurethan, polyamide

#### 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 Legal Requirements

Medical product according to directive MDD 93/42/EEC and the regulation MDR (EU) 2017/745.

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

Packaging

Primary:

folding box made of cellulose

Secondary:

carton made of cellulose

Symbols used in labelling Explanations at <u>www.nobamed.com</u>



Marking on all packaging levels with CE and according to DIN EN ISO 15223-1and ISO 20417.

### Storage and Transport

Dry and dust free

#### Single use device

Intended for use on one patient. The reprocessing of single use devices for reuse can decrease the product's performance significantly. Reusing a single use device can lead to microbiological danger.

#### Disposal

According to locally applicable legal regulations and standards of infection prophylaxis.

Product Data Sheet September 20, 2021 [Rev5], replaces: April 01, 2020 [Rev4]