

NOBAMED Paul Danz AG

HALSKRAWATTE

REF: 373312

Product Description, Intended use, Application

The cervical collar (12 cm, large neck circumference, 43 cm - 48 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]