



RUDA VEN[®]-Air

REF 072212

Product Description, Intended Use Application

The sterile special plaster RUDA VEN[®]-Air of the size **10 cm x 12 cm** consists of a transparent, water vapour permeable polyurethane film. The plaster is provided with a hypoallergenic polyacrylate adhesive. RUDA VEN[®]-Air is used for the secure fixation of cannulas and catheters on the skin. The vascular puncture wound is protected by covering it against germ penetration and contamination and particularly enabling wound observation. The disposable product is individually sterile packed.

Composition

Polyurethane film, polyacrylic adhesive

Contra-Indications

Do not use on infected wounds. Not suitable for wounds that bleed or exude heavily.

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 11135.

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

Packaging

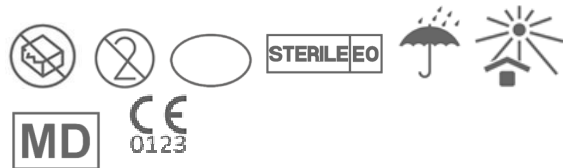
Primary packaging: paper-paper packaging

Secondary packaging: folding box made of cellulose

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, protected from sunlight.

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.