



**NOBAMED Paul Danz AG**

## RUDAPLAST®

**REF 070392**

### **Product Description, Intended use, Application**

The fixing plaster (2.50 cm x 9.14 m) made of textile fabric on a roll with side disks is coated with a zinc oxide adhesive and therefore has a high adhesive strength. It is suitable for fixing wound dressings, bandages, tubes and catheters.

### **Composition**

Viscose, zinc oxide adhesive (colophonium free)

### **Contraindications**

The product should not be used on fragile skin, not on damaged skin and not in the case of a known allergy against the material.

### **Notes**

To avoid swelling and circulatory disorders, fixation tapes are not applied on the extremities under tension in a circular way.

### **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**

RUDAPLAST® is a 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. It has CE marking and DIN EN ISO 15223-1 labels on all its packaging.

### **Packaging**

Primary packaging: folding box made of cellulose

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**

To be stored in a dry and dust-free environment, protected against sunlight.

### **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.