

## *Hospital trays – indispensable for the clinic life*

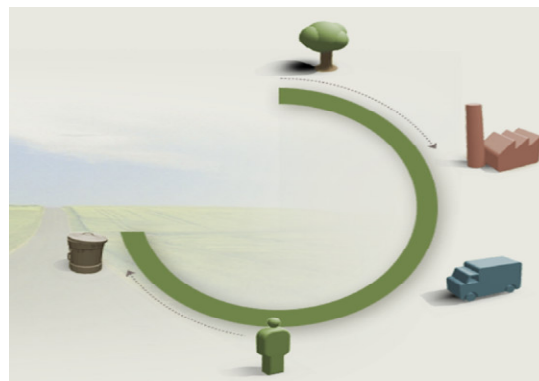
*As part of the European single market and in accordance with the EU Directive all Medical Devices on the European market must carry the CE-mark (Conformité Européenne). Saniclin is a medical device.*

### **Legal overview and labels**

The Council Directive 93/42 EEC of 14 June 1993 describes in general terms the rules for medical devices being placed on the market. In accordance with the Directive all EU and EFTA states must accept CE marked medical devices on their markets.

### **CE Mark**

The trade passport to Europe for a medical device is the CE-mark, which must appear on the product in a visible way, in accordance with the prescription. Manufacturers who have put the CE mark on their products have prepared technical documentation in compliance with the requirements of the Directive. The letters, "CE", indicate that the manufacturer has undertaken all assessment procedures required for the product and may, without restrictions, market the product in the EU and EFTA. The CE mark should not be mistaken for a quality mark or conformity to a standard; rather, it indicates conformity to the legal requirements of the EU Directives.



### **Product requirement**

The Directive implies that information about product design, manufacture, testing and risk must be included in the documentation.

### **Saniclin**

The classification of the product reflects the risk involved in use of the product. Saniclin is a low risk product and belongs to Class I.

As part of the documentation Hartmann has issued a declaration stating that Saniclin complies with the requirements of the Directive. Customers can request a copy of the Declaration of Conformity.

### **The customer**

For the customer the CE mark on Saniclin is a proof of function and safety.

The technical documentation is available in English.

# Saniclin

## Hospital trays – indispensable for the clinic life

### Hospital trays - Easy - Indispensable

#### Saniclin is

- ❖ Practical and easy to use
- ❖ Environmentally friendly
- ❖ Indispensable for hygienic clinic life



#### Saniclin

- ❖ Belongs to modern hospital & clinic life
- ❖ Suitable for universal use, without time consuming and expensive cleaning processes
- ❖ Immediate disposal of used bowls reduces the risk of infection
- ❖ Suitable for macerators

#### The Saniclin kidney bowl keeps its promise

##### **Resistant/impermeable for at least 24 hours to**

- ❖ Sodium chloride 0.9%
- ❖ Hydrogen peroxide 3%,
- ❖ Water 80 °C
- ❖ Acetic acid 5%
- ❖ Chlorhexidine 0.2%

##### **Resistant/impermeable for at least 8 hours**

- ❖ Benzalconium chloride 1%
- ❖ Hydrochloric acid 0.1%

##### **Resistant/impermeable for at least 30 minutes**

- ❖ Alcohol 30%
- ❖ Hot Coffee

### Environment friendly, disposable, Saniclin

- ❖ Made from 100 % recycled paper
- ❖ Not bleached, and does not contain dangerous substances
- ❖ Biodegradable
- ❖ Made from environmentally-friendly natural materials for easy disposal

### EU declaration of conformity

Saniclin conforms to the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices class I.

### Experience and Technology

- ❖ Hartmann has produced moulded fibre products since 1936.
- ❖ Hartmann uses only moulding equipment designed by themselves in the manufacturing process.
- ❖ Production sites are certified to international standards ISO 9001 (quality), and ISO 14001 (environmental).

### Innovation

Quality and delivery performance are key words in our business. Pro-activity, innovation and advanced technology improve our products and create the best solution for you at all times.

### Delivery units

- ❖ 300 units per box
- ❖ One hospital tray weighs 22 gram
- ❖ Brutto weight high pallet: 216,15 kg
- ❖ Net weight: 177,28 kg
- ❖ 8,100 units per pallet (27 boxes)

#### For further information please contact:

Brødrene Hartmann A/S,  
R&D and Sustainability  
Phone: +45 4597 0000  
E-Mail: [Sustainability@hartmann-packaging.com](mailto:Sustainability@hartmann-packaging.com)