

## INFORMS

April/1/2011

# semperguard®

## DUAL LABELLING FOR DUAL PROTECTION

**Semperguard®** protective gloves are developed with Sempermed®'s know-how derived from research for medical products and are manufactured according to the highest quality standards.



The Medical Device Directive 93/42/EEC (amended by Directive 2007/47/EC) enables manufacturers to dual label disposable gloves – i.e. as medical product (protecting the patient) and as personal protective equipment (protecting the user).



Sempermed has decided to introduce this dual labelling for selected products.



### DIRECTIVE ON PERSONAL PROTECTIVE EQUIPMENT 89/686/EEC

- **protecting the user**
- ✓ complies with EN 420 on general requirements for protective gloves
- ✓ complies with **EN 374** on requirements for protective gloves against chemicals and micro-organisms
  -  protection against penetration by micro-organisms
  -  protection against chemical hazards
- ✓ all dual labelled **Semperguard®** gloves are specified as **Category III** (protective equipment for complex risks) and are annually tested by an independent institution

**CE0321** SATRA Technology Centre

**CE0121** IFA - Institut für Arbeitsschutz der Deutschen Gesetzl. Unfallversicherung



### MEDICAL DEVICE DIRECTIVE 93/42/EEC

- **protecting the patient**
- ✓ complies with EN455 on medical gloves
- ✓ complies with **all requirements on safety and documentation** for medical gloves

In addition to the above mentioned Directives and Standards all dual labelled **Semperguard®** gloves comply with

- ✓ **resistance against blood-borne pathogens** according to ASTM F 1671
- ✓ **food safety** according to EU Regulation 1935/2004
- ✓ production according to the principles of **'Good Manufacturing Practice'**
- ✓ **resistance to chemical substances** against certain chemicals (see current resistance list)

The following products of the **Semperguard®** product portfolio will be dual labelled **as of April 2011**:



### SEMPERGUARD® LATEX IC powder free

The all-purpose glove for

- ✓ personal protective
- ✓ pharmacology & laboratory
- ✓ food & catering
- ✓ cleaning & hygiene
- ✓ healthcare
- ✓ house & garden
- ✓ etc



### SEMPERGUARD® NITRILE Comfort powder free

The comfortable nitrile glove with protection against chemical substances for

- ✓ personal protective
- ✓ pharmacology & laboratory
- ✓ food & catering
- ✓ cleaning & hygiene
- ✓ etc

**Semperguard® Nitrile XtraLite** will be dual labelled in **PPE-Category III** as of **May 2011**:



### SEMPERGUARD® NITRILE XtraLite powder free

The thin nitrile glove with high tactile sensitivity and a wearing comfort similar to latex for

- ✓ food & catering
- ✓ cleaning & hygiene
- ✓ healthcare (also for users with latex allergies)
- ✓ house & garden
- ✓ etc

Available in the **environmentally-friendly big pack** (200 pc)

- ✓ less packaging material & waste
- ✓ reduced warehouse logistics
- ✓ less frequent replacement intervals

**As of now the updated specifications and declarations of conformity are available from your Sales Manager.**

Print Information:

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For further information: go to [www.sempermed.com](http://www.sempermed.com)