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**Skyddskläder – Funktionskrav och provnings-  
metoder för skyddskläder mot smittsamma  
ämnen**

**Protective clothing – Performance requirements  
and test methods for protective clothing against  
infective agents**

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
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**EN 14126**

September 2003

ICS 13.340.10

English version

## Protective clothing - Performance requirements and tests methods for protective clothing against infective agents

Vêtements de protection - Exigences de performances et  
méthodes d'essai pour les vêtements de protection contre  
les agents infectieux

Schutzkleidung - Leistungsanforderungen und  
Prüfverfahren für Schutzkleidung gegen Infektionserreger

This European Standard was approved by CEN on 1 August 2003.

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**EN 14126:2003 (E)**

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## **Foreword**

This document (EN 14126:2003) has been prepared by Technical Committee CEN/TC 162 “Protective clothing including hand and arm protection and life jackets”, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2004, and conflicting national standards shall be withdrawn at the latest by March 2004.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative annex ZA, which is an integral part of this document.

Annex A is normative.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

## EN 14126:2003 (E)

### Introduction

Protective clothing against infective agents has two main functions:

- to prevent infective agents from reaching the (possibly injured) skin;
- to prevent the spreading of infective agents to other people and other situations, e.g. eating or drinking, when the person has taken his protective clothing off.

In many work situations, e.g. microbiological laboratories, biotechnological production, etc. the infective agents can be contained and the risk of exposure is limited to the occurrence of an accident. In these situations the agents, to which the worker can be exposed, are usually well known. In other types of work, the organisms can not be contained, exposing the worker continuously to the risk of infection by biological agents. This happens e.g. in sewage work, waste treatment, caring for animals infected with zoonotic agents, emergency clean-up, treatment of hospital risk waste etc. In these situations, the agents the workers are exposed to, may not be known, although possible risks can be assessed.

Micro-organisms are a very heterogeneous group of organisms as to their size, shape, living conditions, infective dose, survival abilities and many other parameters. Their size alone can vary from 30 nm (poliovirus) to 5 µm to 10 µm (bacteria) and even larger (most fungi). A hazard classification of micro-organisms can be found in European Directive 2000/54/EEC (on the protection of workers from the risk related to exposure to biological agents at work).

Due to the heterogeneity of micro-organisms, it is not possible to define performance criteria on the basis of risk groups, nor on the type of micro-organism. Also it may not be possible to define exactly the organisms the worker is exposed to. Hence the test methods specified in this standard focus on the medium containing the micro-organism, such as a liquid, an aerosol or a solid dust particle. A risk analysis should determine which ones of these risks are present in a given situation.

## 1 Scope

This European Standard specifies requirements and test methods for re-usable and limited use protective clothing providing protection against infective agents.

Clothing worn by surgical teams or drapes laid on patients to prevent cross-contamination during surgical interventions are not covered by the scope of this standard.

## 2 Normative references

This European standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 340 <sup>1)</sup>, *Protective clothing — General requirements.*

EN 465 <sup>1)</sup>, *Protective clothing — Protection against liquid chemicals – Performance requirements for chemical protective clothing with spray-tight connections between different parts of the clothing (Type 4 Equipment).*

EN 466 <sup>1)</sup>, *Protective clothing — Protection against liquid chemicals – Performance requirements for chemical protective clothing with liquid-tight connections between different parts of the clothing (Type 3 Equipment).*

EN 467 <sup>1)</sup>, *Protective clothing — Protection against liquid chemicals – Performance requirements for garments providing protection to parts of the body.*

EN 868-1, *Packaging materials and systems for medical devices which are to be sterilized - Part 1: General requirements and test methods.*

EN 943-1, *Protective clothing against liquid and gaseous chemicals, including liquid aerosols and solid particles — Part 1: Performance requirements for ventilated and non-ventilated “gas-tight” (Type 1) and “non-gas-tight” (Type 2) chemical protective suits.*

EN 943-2, *Protective clothing against liquid and gaseous chemicals, including liquid aerosols and solid particles — Part 2: Performance requirements for “gas-tight” (Type 1) chemical protective suits for emergency teams (ET).*

prEN 13034, *Protective clothing for use against liquid chemicals — Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (type 6 equipment).*

EN 13795-1, *Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical stuff and equipment - Part 1: General requirements for manufacturers, processors and products.*

prEN ISO 13982-1, *Protective clothing for use against solid particulate chemicals — Part 1: Performance requirements for chemical protective clothing providing protection to the full body against solid particulate chemicals (type 5 clothing) (ISO/DIS 13982-1:2000).*

prEN 14325, *Protective clothing against chemicals — Test methods and performance classification of chemical protective clothing materials, seams, joins and assemblages.*

ISO 139, *Textiles; Standard atmospheres for conditioning and testing.*

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1) revision currently in progress

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prCEN ISO/TR 11610, *Protective clothing — Glossary of terms and definitions. (ISO/DTR 11610:2002)*

ISO/FDIS 16603, *Clothing for protection against contact with blood and body fluids — Determination of the resistance of protective clothing materials to penetration by blood and body fluids — Test method using synthetic blood.*

ISO/FDIS 16604, *Clothing for protection against contact with blood and body fluids — Determination of resistance of protective clothing materials to penetration by blood-borne pathogens — Test method using Phi-X-174 Bacteriophage.*

ISO/DIS 22611, *Clothing for protection against infectious agents — Test method for resistance to penetration by biologically contaminated aerosols.*

ISO/DIS 22612, *Clothing for protection against infectious agents — Test method for resistance to penetration by biologically contaminant dust through protective clothing materials.*

### 3 Terms and definitions

For the purposes of this European Standard, the terms and definitions of prCEN ISO/TR 11610:2003 and the following terms and definitions apply.

**3.1 infective agents**  
micro-organisms, including those which have been genetically modified, cell cultures and human endoparasites, which may be able to provoke any infection, allergy or toxicity <sup>2)</sup>

**3.2 protective clothing against biological agents**  
combined assembly of garments, intended to afford protection to the skin against exposure to or contact with infective agents

**3.3 protective clothing material against infective agents**  
any material or combination of materials used in an item of protective clothing for the purpose of isolating parts of the body from direct contact with an infective agent

**3.4 protective suit against infective agents**  
suit protecting against infective agents which can be hazardous to the health. A suit may have various types of additional protection such as a hood or helmet, boots and gloves

### 4 Requirements

#### 4.1 Materials requirements

##### 4.1.1 General

If the care instructions indicate that the clothing can be cleaned and reprocessed at least five times, protective clothing materials shall be submitted to five cleaning and reprocessing cycles according to the manufacturer's care instructions before testing.

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<sup>2)</sup> European Directive 90/679/EEC on the protection of workers from the risk related to exposure to biological agents at work.

If the care instructions specify a lower number of cleaning/reprocessing cycles, then materials shall be submitted to the number of cleaning/reprocessing cycles indicated.

Unless otherwise stated in the relevant test procedure, the specimens shall be conditioned for at least 24 h in an atmosphere of  $(20 \pm 2)$  °C and  $(65 \pm 5)$  % relative humidity before testing. Tests shall be carried out in the same atmosphere or within 5 min of removing the sample from the conditioning atmosphere.

#### 4.1.2 Mechanical and flammability requirements

The materials shall be tested and classified in accordance with the test methods and performance classification system specified in the relevant clauses of prEN 14325.

#### 4.1.3 Chemical requirements

If protection against chemicals is claimed, the materials shall be tested and classified in accordance with the test methods and performance classification system specified in the relevant clauses of prEN 14325.

#### 4.1.4 Performance requirements against penetration by infective agents

##### 4.1.4.1 Resistance to penetration by contaminated liquids under hydrostatic pressure

When tested in accordance with ISO/FDIS 16603 and ISO/FDIS 16604 the material shall be classified according to the levels of performance given in Table 1, as obtained in the bacteriophage test (ISO/FDIS 16604).

NOTE The synthetic blood test (ISO/FDIS 16603) is used for screening purposes, i.e. to predict the level where a strikethrough can be expected when performing the bacteriophage test (ISO/FDIS 16604)

**Table 1 — Classification of resistance to penetration by contaminated liquids under hydrostatic pressure (ISO/FDIS 16604)**

Class	Hydrostatic pressure at which the material passes the test
6	20 kPa
5	14 kPa
4	7 kPa
3	3,5 kPa
2	1,75 kPa
1	0 kPa <sup>a</sup>
<sup>a</sup> this means that the material is only exposed to the hydrostatic pressure of the liquid in the test cell	

##### 4.1.4.2 Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids.

When tested in accordance with Annex A the material shall be classified according to the levels of performance given in Table 2.

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**Table 2 — Classification of resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids**

<b>Class</b>	<b>Breakthrough time, <i>t</i> min</b>
6	$t > 75$
5	$60 < t \leq 75$
4	$45 < t \leq 60$
3	$30 < t \leq 45$
2	$15 < t \leq 30$
1	$\leq 15$ min

**4.1.4.3 Resistance to penetration by contaminated liquid aerosols**

When tested in accordance with ISO/DIS 22611 the material shall be classified according to the levels of performance given in Table 3.

**Table 3 — Classification of resistance to penetration by contaminated liquid aerosols**

<b>Class</b>	<b>Penetration ratio (log)</b>
3	$\log > 5$
2	$3 < \log \leq 5$
1	$1 < \log \leq 3$

**4.1.4.4 Resistance to penetration by contaminated solid particles.**

When tested in accordance with ISO/DIS 22612 the material shall be classified according to the levels of performance given in Table 4.

**Table 4 — Classification of resistance to penetration by contaminated solid particles**

<b>Class</b>	<b>Penetration (log cfu)</b>
3	$\leq 1$
2	$1 < \log \text{ cfu} \leq 2$
1	$2 < \log \text{ cfu} \leq 3$

**4.2 Performance requirements for seams, joins and assemblages**

Seams, joins and assemblages of protective clothing against infective agents shall fulfil the requirements specified in the relevant clauses of prEN 14325 Seam strength shall be classified according to 5.5 of prEN 14325:2001.

### **4.3 Whole suit requirements**

Protective clothing against infective agents shall fulfil the relevant requirements of EN 340 and the whole suit requirements specified in the relevant standard for chemical protective clothing (see Table 5).

The materials and design used shall not cause skin irritation nor have any adverse effect to health.

NOTE The suit should be as light and as flexible as possible in order to ensure the comfort of the wearer, not to hinder movements and still provide at the same time effective protection.