

ANNEX II

BASIC HEALTH AND SAFETY REQUIREMENTS

1. GENERAL REQUIREMENTS APPLICABLE TO ALL PPE

PPE must provide adequate protection against all risks encountered.

1.1. Design principles

1.1.1. Ergonomics

PPE must be so designed and manufactured that in the foreseeable conditions of use for which it is intended the user can perform the risk-related activity normally whilst enjoying appropriate protection of the highest possible level.

1.1.2. Levels and classes of protection

1.1.2.1. Highest level of protection possible

The optimum level of protection to be taken into account in the design is that beyond which the constraints imposed by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or normal performance of the activity.

1.1.2.2. Classes of protection appropriate to different levels of risk

Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.

1.2. Innocuousness of PPE

1.2.1. Absence of risks and other 'inherent' nuisance factors

PPE must be so designed and manufactured as to preclude risks and other nuisance factors under foreseeable conditions of use.

1.2.1.1. Suitable constituent materials

PPE materials and parts, including any of their decomposition products, must not adversely affect user hygiene or health.

1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user

Any PPE part in contact or in potential contact with the user when such equipment is worn must be free of roughness, sharp edges, projections and the like which could cause excessive irritation or injuries.

1.2.1.3. Maximum permissible user impediment

Any impediment caused by PPE to movements to be made, postures to be adopted and sensory perception must be minimized; nor must PPE cause movements which endanger the user or other persons.

1.3. Comfort and efficiency

1.3.1. Adaptation of PPE to user morphology

PPE must be so designed and manufactured as to facilitate correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, movements

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to be made and postures to be adopted. For this purpose, it must be possible to optimize PPE adaptation to user morphology by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate size range.

1.3.2. Lightness and design strength

PPE must be as light as possible without prejudicing design strength and efficiency.

Apart from the specific additional requirements which they must satisfy in order to provide adequate protection against the risks in question (see 3), PPE must be capable of withstanding the effects of ambient phenomena inherent under the foreseeable conditions of use.

1.3.3. Compatibility of different classes or types of PPE designed for simultaneous use

If the same manufacturer markets several PPE models of different classes or types in order to ensure the simultaneous protection of adjacent parts of the body against combined risks, these must be compatible.

1.4. Information supplied by the manufacturer

In addition to the name and address of the manufacturer and/or his authorized representative established in the Community, the notes that must be drawn up by the former and supplied when PPE is placed on the market must contain all relevant information on:

- (a) storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products recommended by manufacturers must have no adverse effect on PPE or users when applied in accordance with the relevant instructions;
- (b) performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in question;
- (c) suitable PPE accessories and the characteristics of appropriate spare parts;
- (d) the classes of protection appropriate to different levels of risk and the corresponding limits of use;
- (e) the obsolescence deadline or period of obsolescence of PPE or certain of its components;
- (f) the type of packaging suitable for transport;
- (g) the significance of any markings (see 2.12).
- (h) [^{F1}where appropriate, the references of the Directives applied in accordance with Article 5 (6) (b);
- (i) the name, address and identification number of the notified body involved in the design stage of the PPE.]

Textual Amendments

- F1** Inserted by Council Directive 93/68/EEC of 22 July 1993 amending Directives 87/404/EEC (simple pressure vessels), 88/378/EEC (safety of toys), 89/106/EEC (construction products), 89/336/EEC (electromagnetic compatibility), 89/392/EEC (machinery), 89/686/EEC (personal protective equipment), 90/384/EEC (non-automatic weighing instruments), 90/385/EEC (active implantable medicinal devices), 90/396/EEC (appliances burning gaseous fuels), 91/263/EEC (telecommunications terminal equipment),

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92/42/EEC (new hot-water boilers fired with liquid or gaseous fuels) and 73/23/EEC (electrical equipment designed for use within certain voltage limits).

These notes, which must be precise and comprehensible, must be provided at least in the official language(s) of the Member State of destination.