L.N. 122 of 1998

QUALITY CONTROL (EXPORTS, IMPORTS AND LOCAL GOODS) ACT (CAP. 225)

Personal Protective Equipment Order 1998 (Order No. M34 of 1998)

IN exercise of the powers conferred by section 3 of the Quality Control (Exports, Imports and Local Goods) Act, the Malta Standardisation Authority has made the following order:—

Citation and commencement.

1.1. This Order may be cited as the Personal Protective Equipment Order, 1998 and may be referred to as Order No. M34 of 1998.

1.2. This Order shall become operative on the 1st July, 1998, which date shall be notified by the Authority in the Gazette.

1.2.1. Provided that the requirement of paragraph 6 of this Order and the CE marking shall not be obligatory prior to the 1st January, 1999 in respect of:

1.2.1.1. stocks of personal protective equipment already placed on the market prior to the 1st July, 1998;

1.2.1.2. personal protective equipment ordered before the 1st July, 1998 and imported into Malta up to the 31st December, 1998.

Scope.

2.1. This Order shall apply to personal protective equipment, hereinafter referred to as "PPE", but does not apply to those classes specified in the list of excluded products in Schedule 1 of this Order.

Definitions.

3.1. In this Order —

3.1.1. "PPE" shall mean:

3.1.1.1. any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards;

3.1.1.2. a unit constituted by several devices or appliances which have been integrally combined by the manufacturer for the protection of an individual against one or more potentially simultaneous risks;

3.1.1.3. a protective device or appliance combined, separably or inseparably with personal non-protective equipment worn or held by an individual for the execution of a specific activity;

3.1.1.4. interchangeable PPE components which are essential to its satisfactory functioning and used exclusively for such equipment.

3.1.2. "approved body" means a body approved to carry out EC type examination as laid down in the Directive. The names of such approved bodies are published in the Official Journal of the European Communities.

3.1.3. "the Directive" means Council Directive 89/686/EEC (OJ No. L 399, 30-12-89, p.18) as amended by Council Directive 93/95/ EEC (OJ No. L 276, 09-11-93, p. 11), Council Directive 93/68/EEC (OJ No. L 220, 30-08-93, p. 1) and Council Directive 96/58/EC (OJ No. L 236, 18-09-96, p. 44) on the approximation of the laws of the Member States relating to personal protective equipment.

3.1.4. "Harmonised Standard" means a technical specification adopted by the European Committee for Standardisation (CEN) or the European Committee for Electrotechnical Standardisation (CENELEC) or both, upon a remit from the European Commission in accordance with Council Directive 83/189/EEC (OJ No. L 109, 26-04-83, p. 8) laying down a procedure for the provision of information in the field of technical standards and regulations.

3.1.5. "National Standard transposing the Harmonised Standard" means a Standard issued by one of the members of CEN which is declared and noted to be technically equivalent to the Harmonised Standard originally issued by CEN.

3.1.6. "OJ" means The Official Journal of the European Communities.

3.1.7. "Community" means the European Community.

3.1.8. "CE marking" means marking as set out in Schedule 4 of this Order.

3.1.9. "placing on the market" means importation, wholesale, retail sale and distribution free of charge.

3.1.10. "authorised representative" means a person appointed by the manufacturer to act on his behalf in fulfilling his obligations under this Order and recognised by the Malta Standardisation Authority as acting in this capacity.

3.1.11. "responsible person" in relation to PPE means:

(a) the manufacturer thereof;

(b) the manufacturer's authorised representative; or

(c) where the manufacturer is not established in Malta and he has not appointed an authorised representative, the person who places the PPE on the market.

Applicability.

4.1. The provisions of this Order are applicable to all imported PPE as well as those manufactured for the local market.

4.2. Subject to paragraph 4.3 below, the provisions of this Order shall not apply to PPE which the responsible person believes (with reasonable cause) will not be used in Malta and hence intended exclusively for export.

4.3. Subject to paragraph 10 below, paragraph 4.2 above shall not apply if the CE marking or any inscription liable to be confused therewith is affixed to the PPE.

Conformity.

5.1. PPE referred to in paragraph 2.1. of this Order may be placed on the market and brought into service only if it preserves the health and ensures the safety of users without prejudice to the health or safety of other individuals, domestic animals or goods, when properly maintained and used for its intended purpose.

5.2. Subject to the prior written approval of the Malta Standardisation Authority, the presentation at trade fairs, exhibitions and the like of PPE which is not in conformity with the provisions of this Order, provided that an appropriate notice is displayed drawing attention to this fact and the prohibition on its acquisition and/or use for any purpose whatsoever until it has been brought into conformity by the responsible person, shall not be precluded.

5.3. PPE referred to in paragraph 2.1. of this Order must satisfy the basic health and safety requirements laid down in Schedule 2 of this Order.

5.4. The placing on the market of PPE or PPE components which comply with the provisions of the Directive and which bear the CE marking attesting their conformity to all the provisions of the Directive including the certification procedures laid down in Chapter II of the Directive shall not be prohibited, restricted or hindered.

5.5. The placing on the market of PPE components which do not bear the CE marking and which are intended to be incorporated in PPE shall not be prohibited, restricted or impeded provided that they are not essential to the satisfactory functioning of the PPE.

CE marking and certificates of conformity.

6.1. PPE referred to in paragraph 8.3 of this Order bearing the CE marking with respect to which the manufacturer is able to produce, on demand, the declaration of conformity referred to in paragraph 9 of this Order, shall be regarded as in conformity with the basic requirements referred to in paragraph 5.3. of this Order .

6.2. It shall be presumed that the PPE referred to in paragraph 8.2 of this Order satisfies the basic requirements referred to in paragraph 5.3. of this Order if it bears the CE marking with respect to which the manufacturer is able to produce, on demand, not only the declaration referred to in paragraph 9 of this Order but also the certificate issued by an approved body attesting to their conformity to the relevant National Standards transposing the Harmonised Standards, assessed at the EC type examinations level in accordance with the first indent of Article 10 (4) (a) and (b) of the Directive.

6.3. Where a manufacturer has not applied or has only partly applied, the Harmonised Standards or, where there are no such standards the certificate issued by the approved body must state the conformity to the basic requirements in accordance with the second indent of Article 10 (4) (a) and (b) of the Directive.

6.4. Where the PPE is subject to other Directives concerning other aspects which also provide for the affixing of the CE marking, the latter shall indicate that the PPE is also presumed to conform to the provisions of the other Directives.

6.4.1. However, where one or more of these Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity to the provisions only of those Directives applied by the manufacturer. In this case, particulars of the Directives applied, as published in the *Official Journal of the European Communities,* must be given in the documents, notices or instructions required by the Directives and accompanying such PPE.

Withdrawal and prohibition from market.

7.1. If it is discovered that PPE bearing the CE marking and used in accordance with its intended purpose could compromise the safety of individuals, domestic animals or property, all necessary measures shall be taken to remove that equipment from the market and prohibit the marketing or free movement thereof.

8.1. Before placing a PPE model on the market, the manufacturer established in Malta, shall assemble the technical documentation referred to in Schedule 3 of this Order so that this can, if necessary, be submitted to the Malta Standardisation Authority. Certification procedures.

8.1.1. Where the manufacturer is not established in Malta, his authorised representative as recognised by the Malta Standardisation Authority or the person who places the PPE on the local market shall be responsible for the provision of the documentation referred to in paragraph 8.1 of this Order, on demand by the Malta Standardisation Authority within a period of two weeks from the date of being so requested.

8.2. Prior to the series production of PPE other than those referred to in paragraph 8.3. of this Order, the manufacturer or his authorised representative, as recognised by the Malta Standardisation Authority, shall submit a model for EC type-examination whereby the approved body establishes and certifies that the PPE model in question satisfies the relevant provisions of this Order.

8.3. An EC type-examination shall not be required in the case of PPE models of simple design where the manufacturer assumes the user can himself assess the level of protection provided against the minimal risks concerned the effects of which, when they are gradual, can be safely identified by the user in good time.

8.3.1. This category shall cover exclusively PPE intended to protect the wearer against:

— mechanical action whose effects are superficial (gardening gloves, thimbles, etc.),

— cleaning materials of weak action and easily reversible effects (gloves affording protection against diluted detergent solutions, etc.),

— risks encountered in the handling of hot components which do not expose the user to temperature exceeding 50°C or to dangerous impacts (gloves, aprons for professional use, etc.),

— atmospheric agents of a neither exceptional nor extreme nature (headgear, seasonal clothing, footwear, etc.),

— minor impacts and vibrations which do not affect vital areas of the body and whose effects cannot cause irreversible lesions (light anti-scalping helmets, gloves, light footwear, etc.),

— sunlight (sunglasses).

8.4. Production of PPE shall be subject:

8.4.1. according to the manufacturer's choice, to one of the two procedures referred to in Article 11 of the Directive regarding the checking of manufactured PPE. This shall apply in the case of PPE of complex design intended to protect against mortal danger or against dangers that may seriously and irreversibly harm the health, the immediate effects of which the designer assumes the user cannot identify in sufficient time. This category shall cover exclusively:

— filtering respiratory devices for protection against solid and liquid aerosols or irritant, dangerous, toxic or radiotoxic gases,

— respiratory protection devices providing full insulation from the atmosphere, including those for use in diving,

— PPE providing only limited protection against chemical attack or against ionising radiation,

— emergency equipment for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100°C or more and which may or may not be characterised by the presence of infra-red radiation, flames or the projection of large amounts of molten material,

— emergency equipment for use in low-temperature environments the effects of which are comparable to those of an air temperature of -50°C or less,

— PPE to protect against falls from a height,

— PPE against electrical risks and dangerous voltages or that are used as insulation in high-tension work.

8.4.2. to the declaration of conformity referred to in paragraph 9 of this Order for all PPE.

Declaration of production conformity.

9.1. The declaration of conformity is the procedure whereby the manufacturer or his authorised representative as recognised by the Malta Standardisation Authority:

9.1.1. draws up a declaration using the form laid down in Schedule 5 of this Order certifying that the PPE placed on the market are in conformity with the provisions of this Order, with a view to its submission to the Malta Standardisation Authority,

9.1.2. affixes the CE marking provided for in paragraph 10 of this Order.

10.1. The CE conformity marking shall consist of the initials "CE" in the form shown in the specimen in Schedule 4. In the event of the involvement of a notified body in the production control phase as indicated in Article 11 of the Directive, its identification number shall be added. CE conformity marking.

10.2. The CE marking must be affixed to each piece of manufactured PPE so as to be visible, legible and indelible throughout the expected life of the PPE; however, if this is not possible in view of the characteristics of the product, the CE marking may be affixed to its packaging.

10.3. The affixing of markings on the PPE which are likely to deceive third parties as to the meaning and form of the CE marking shall be prohibited. Any other marking may be affixed to the PPE or its packaging provided that the visibility and legibility of the CE marking is not thereby reduced.

10.4. Without prejudice to paragraph 7:

10.4.1. where it is established that the CE marking has been affixed unduly, the responsible person shall be obliged to make the product conform as regards the provisions concerning the CE marking and to end the infringement, under the conditions imposed by the Malta Standardisation Authority.

10.4.2. where non-conformity continues, all appropriate measures shall be taken to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in paragraph 7.

SCHEDULE 1

ANNEX I OF THE DIRECTIVE

EXHAUSTIVE LIST OF PPE CLASSES NOT COVERED BY THIS DIRECTIVE

1. PPE designed and manufactured specifically for use by the armed forces or in the maintenance of law and Order (helmets, shields, etc.).

2. PPE for self-defence (aerosol canisters, personal deterrent weapons, etc.).

3. PPE designed and manufactured for private use against:

— adverse atmospheric conditions (headgear, seasonal clothing, footwear, umbrellas, etc.),

— damp and water (dish-washing gloves, etc.),

— heat (gloves etc.).

4. PPE intended for the protection or rescue of persons on vessels or aircraft, not worn all the time.

5. Helmets and visors intended for users of two or three-wheeled motor vehicles.

SCHEDULE 2

ANNEX II OF THE DIRECTIVE

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 minimised; 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 to be made and postures to be adopted. For this purpose, it must be possible to optimise 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 item 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 of the person placing the PPE on the market, the notes that must be drawn up by the former and supplied whenever PPE is placed on the market must contain all relevant information on:

(a) storage, use, cleaning, maintenance, servicing and disinfecting. 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 paragraph 2.12);

(h) where appropriate, the references of the Directives applied in accordance with paragraph 6.4.1 of this Order;

(i) the name, address and identification number of the notified body involved in the design stage of the PPE.

These notes, which must be precise and comprehensible, must be provided at least in Maltese or English.

2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL CLASSES OR TYPES OF PPE

2.1. PPE incorporating adjustment systems

If PPE incorporates adjustment systems, the latter must be so designed and manufactured as not to become incorrectly adjusted without the user's knowledge under the foreseeable conditions of use.

2.2. PPE 'enclosing' the parts of the body to be protected

As far as possible, PPE 'enclosing' the parts of the body to be protected must be sufficiently ventilated to limit perspiration resulting from use; if this is not the case, it must if possible be equipped with devices which absorb perspiration.

2.3. PPE for the face, eyes and respiratory tracts

Any restriction of the user's field of vision or sight by PPE for the face, eyes or respiratory tract must be minimised.

The degree of optical neutrality of the vision systems of these PPE classes must be compatible with the type of relatively meticulous and/or prolonged activities of the user.

If necessary, they must be treated or provided with facilities to prevent moisture formation.

PPE models intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.

2.4. PPE subject to ageing

If it is known that the design performances of new PPE may be significantly affected by ageing, the date of manufacture and/or, if possible, the date of obsolescence, must be indelibly inscribed on every PPE item or interchangeable component placed on the market in such a way as to preclude any misinterpretation; this information must also be indelibly inscribed on the packaging.

If a manufacturer is unable to give an undertaking with regard to the useful life of PPE, his notes must provide all the information necessary to enable the purchaser or

user to establish a reasonable obsolescence date, bearing in mind the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.

Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a mark to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded; failing that, the manufacturer must give this information in his notes.

2.5. **PPE which may be caught up during use**

Where the foreseeable conditions of use include in particular the risk of the PPE being caught up by a moving object thereby creating a danger for the user, the PPE must possess an appropriate resistance threshold above which a constituent part will break and eliminate the danger.

2.6. **PPE for use in explosive atmospheres**

PPE intended for use in explosive atmospheres must be so designed and manufactured that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.

2.7. **PPE intended for emergency use or rapid installation and/or removal**

These PPE classes must be so designed and manufactured as to minimise the time required for attachment and/or removal.

Any integral systems permitting correct positioning on, or removal from, the user must be susceptible of rapid and easy operation.

2.8. **PPE for use in very dangerous situations**

The information notes supplied by the manufacturer together with PPE for use in the very dangerous situations referred to in paragraph 8.4.1. of this order must include, in particular, data intended for the exclusive use of competent trained individuals who are qualified to interpret them and ensure their application by the user.

They must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.

If PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, this must be so designed and accommodated as to be perceived by the user in the conditions of use for which the PPE is marketed.

2.9. **PPE incorporating components which can be adjusted or removed by the user**

Any PPE components which can be adjusted or removed by the user for the purpose of replacement must be so designed and manufactured as to facilitate adjustment, attachment and removal without tools.

2.10. **PPE for connection to another, external complementary device**

If PPE incorporates a system permitting connection to another, complementary, device, the attachment mechanism must be so designed and manufactured as to enable it to be mounted only on appropriate equipment.

2.11. **PPE incorporating a fluid circulation system**

If PPE incorporates a fluid circulation system, the latter must be so chosen, or designed, and incorporated as to permit adequate fluid renewal in the vicinity of the entire part of the body to be protected, irrespective of user gestures, posture or movement under the foreseeable conditions of use.

2.12. **PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety**

The identification or recognition marks directly or indirectly relating to health and safety affixed to these types or classes of PPE must preferably take the form of harmonised pictograms or ideograms and must remain perfectly legible throughout the foreseeable useful life of the PPE. In addition, these marks must be complete, precise and comprehensible so as to prevent any misinterpretation; in particular, when such marks incorporate words or sentences, the latter must appear at least in Maltese or English.

If PPE (or PPE component) is too small to allow all or part of the necessary marking to be affixed, the relevant information must be mentioned on the packing and in the manufacturer's notes.

2.13. **PPE in the form of clothing capable of signalling the user's presence visually**

PPE in the form of clothing intended for foreseeable conditions of use in which the user's presence must be visibly and individually signalled must have one (or more) judiciously positioned means of or devices for emitting direct or reflected visible radiation of appropriate luminous intensity and photometric and colorimetric properties.

2.14. **'Multi-risk' PPE**

All PPE designed to protect the user against several potentially simultaneous risks must be so designed and manufactured as to satisfy, in particular, the basic requirements specific to each of those risks (see item 3).

3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

3.1. **Protection against mechanical impact**

3.1.1. *Impact caused by falling or projecting objects and collision of parts of the body with an obstacle.*

Suitable PPE for this type of risk must be sufficiently shock-absorbent to prevent injury resulting, in particular, from the crushing or penetration of the protected part, at least up to an impact-energy level above which the excessive dimensions or mass of the absorbing device would preclude effective use of the PPE for the foreseeable period of wear.

3.1.2. *Falls*

3.1.2.1. Prevention of falls due to slipping

The outsoles for footwear designed to prevent slipping must be so designed, manufactured or equipped with added elements as to ensure satisfactory adhesion by grip and friction having regard to the nature or state of the relative surface.

3.1.2.2. Prevention of falls from a height

PPE designed to prevent falls from a height or their effects must incorporate a body harness and an attachment system which can be connected to a reliable anchorage point. It must be designed so that under the foreseeable conditions of use the vertical drop of the user is minimised to prevent collision with obstacles and the braking force does not, however, attain the threshold value at which physical injury or the tearing or rupture of any PPE component which might cause the user to fall, can be expected to occur.

It must also ensure that after braking the user is maintained in a correct position in which he may await help if necessary.

The manufacturer's notes must specify in particular all relevant information relating to:

- the characteristics required for the reliable anchorage point and the necessary minimum clearance below the user,

- the proper way of putting on the body harness and of connecting the attachment system to the reliable anchorage point.

3.1.3. *Mechanical vibration*

PPE designed to prevent the effects of mechanical vibrations must be capable of ensuring adequate attenuation of harmful vibration components for the part of the body at risk.

Under no circumstances must the effective value of the accelerations transmitted to the user by those vibrations exceed the limit values recommended in the light of the maximum foreseeable daily exposure of the part of the body at risk.

3.2. **Protection against (static) compression of part of the body**

PPE designed to protect part of the body against (static) compressive stress must be sufficiently capable of attenuating its effects to prevent serious injury or chronic complaints.

3.3. **Protection against physical injury (abrasion, perforation, cuts, bites)**

PPE constituent materials and other components designed to protect all or part of the body against superficial injury caused by machinery, such as abrasion, perforation, cuts or bites, must be so chosen or designed and incorporated as to ensure that these PPE classes provide sufficient resistance to abrasion, perforation and gashing (see also paragraph 3.1) under the foreseeable conditions of use.

3.4. **Prevention of drowning (lifejackets, armbands and lifesaving suits)**

PPE designed to prevent drowning must be capable of returning to the surface as quickly as possible, without danger to the health of a user who may be exhausted or unconscious after falling into a liquid medium, and of keeping him afloat in a position which permits breathing while awaiting help.

PPE may be wholly or partially inherently buoyant, or may be inflated either by gas which can be manually or automatically released, or orally.

Under the foreseeable conditions of use:

- PPE must, without prejudice to its satisfactory operation, be capable of withstanding the effects of impact with the liquid medium and the environmental factors inherent in that medium,

- inflatable PPE must be capable of inflating rapidly and fully.

Where particular foreseeable conditions of use so require, certain types of PPE must also satisfy one or more of the following additional requirements:

- it must have all the inflation devices referred to in the second subparagraph, and/or a light or sound-signalling device,

- it must have a device for hitching and attaching the body so that the user may be lifted out of the liquid medium,

- it must be suitable for prolonged use throughout the period of activity exposing the user, possibly dressed, to the risk of falling into the liquid medium or requiring his immersion in it.

3.4.1. *Buoyancy aids*

Clothing which will ensure an effective degree of buoyancy, depending on its foreseeable use, which is safe when worn and which affords positive support in water. In foreseeable conditions of use, this PPE must not restrict the user's freedom of movement but must enable him, in particular, to swim or take action to escape from danger or rescue other persons.

3.5. **Protection against the harmful effects of noise**

PPE designed to prevent the harmful effects of noise must be capable of attenuating the latter to such an extent that the equivalent sound levels perceived by the user do not under any circumstances exceed the daily limit values laid down by Council Directive 86/188/EEC of 12 May 1986 on the protection of workers from the risk related to exposure to noise at work (OJ No. L 137, 24.5.1986, p.28).

All PPE must bear labelling indicating the noise attenuation level and the value of the comfort index provided by the PPE; should this not be possible, the labelling must be fixed to the packaging.

3.6. **Protection against heat and/or fire**

PPE designed to protect all or part of the body against the effects of heat and/or fire must possess thermal insulation capacity and mechanical strength appropriate to foreseeable conditions of use.

3.6.1. *PPE constituent materials and other components*

Constituent materials and other components suitable for protection against radiant and convective heat must possess an appropriate coefficient of transmission of incident heat flux and be sufficiently incombustible to preclude any risk of spontaneous ignition under the foreseeable conditions of use.

Where the outside of these materials and components must be reflective, its reflective power must be appropriate to the intensity of the heat flux due to radiation in the infra-red range.

Materials and other components of equipment intended for brief use in high-temperature environments and of PPE which may be splashed by hot products such as large quantities of molten material must also possess sufficient thermal capacity to retain most of the stored heat until after the user has left the danger area and removed his PPE.

PPE materials and other components which may be splashed by large amounts of hot products must also possess sufficient mechanical-impact absorbency (see paragraph 3.1).

PPE materials and other components which may accidentally come into contact with flame and those used in the manufacture of fire-fighting equipment must also possess a degree of non-flammability corresponding to the risk class associated with the foreseeable conditions of use. They must not melt when exposed to flames nor contribute to flame propagation.

3.6.2. *Complete PPE ready for use*

Under the foreseeable conditions of use:

1. The quantity of heat transmitted by PPE to the user must be sufficiently low to prevent the heat accumulated during wear in the part of the body at risk from attaining, under any circumstances, the pain or health impairment threshold;

2. PPE must, if necessary, prevent liquid or steam penetration and must not cause burns resulting from contact between its protective integument and the user.

If PPE incorporates refrigeration devices for the absorption of incident heat by means of liquid evaporation or solid sublimation, their design must be such that any volatile substances released are discharged beyond the outer protective integument and not towards the user.

If PPE incorporates a breathing device, the latter must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.

The manufacturer's notes accompanying each PPE model intended for brief use in high-temperature environments must in particular provide all relevant data for the determination of the maximum permissible user exposure to the heat transmitted by the equipment when used in accordance with its intended purpose.

3.7. **Protection against cold**

PPE designed to protect all or part of the body against the effects of cold must possess thermal insulating capacity and mechanical strength appropriate to the foreseeable conditions of use for which it is marketed.

3.7.1. *PPE constituent materials and other components*

Constituent materials and other components suitable for protection against cold must possess a coefficient of transmission of incident thermal flux as low as required under the foreseeable conditions of use. Flexible materials and other components of PPE intended for use in a low-temperature environment must retain the degree of flexibility required for the necessary gestures and postures.

PPE materials and other components which may be splashed by large amounts of cold products must also possess sufficient mechanical-impact absorbency (see paragraph 3.1).

3.7.2. *Complete PPE ready for use*

Under the foreseeable conditions of use:

1. the flux transmitted by PPE to the user must be sufficiently low to prevent the cold accumulated during wear at any point on the part of the body being protected, including the tips of fingers and toes in the case of hands or feet, from attaining, under any circumstances, the pain or health-impairment threshold;

2. PPE must as far as possible prevent the penetration of such liquids as rain water and must not cause injuries resulting from contact between its cold protective integument and the user.

If PPE incorporates a breathing device, this must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.

The manufacturer's notes accompanying each PPE model intended for brief use in low-temperature environments must provide all relevant data concerning the maximum permissible user exposure to the cold transmitted by the equipment.

3.8 **Protection against electric shock**

PPE designed to protect all or part of the body against the effects of electric current must be sufficiently insulated against the voltages to which the user is likely to be exposed under the most unfavourable foreseeable conditions.

To this end, the constituent materials and other components of these PPE classes must be so chosen or designed and incorporated as to ensure that the leakage current measured through the protective integument under test conditions at voltages correlated with those likely to be encountered *in situ* is minimised and, at all events, below a maximum conventional permissible value which correlates with the tolerance threshold.

Together with their packaging, PPE types intended exclusively for use during work or activities in electrical installations which are or may be under tension must bear markings indicating, in particular, their protection class and (or) corresponding

operating voltage, their serial number, and their date of manufacture; a space must also be provided outside the protective integument of such PPE for the subsequent inscription of the date of entry into service and those of the periodic tests or inspections to be conducted.

The manufacturer's notes must indicate, in particular, the exclusive use for which these PPE types are intended and the nature and frequency of the dielectric tests to which they are to be subjected during their useful life.

3.9. **Radiation Protection**

3.9.1. *Non-ionising radiation*

PPE designed to prevent acute or chronic eye-damage from sources of non-ionising radiation must be capable of absorbing or reflecting the majority of the energy radiated in the harmful wavelengths without unduly affecting the transmission of the innocuous part of the visible spectrum, the perception of contrasts and the ability to distinguish colours where required by the foreseeable conditions of use.

To this end, protective glasses must be so designed and manufactured as to possess, for each harmful wave, a spectral transmission factor such that the radiant-energy illumination density capable of reaching the user's eye through the filter is minimised and, under no circumstances, exceeds the maximum permissible exposure value.

Furthermore, the glasses must not deteriorate or lose their properties as a result of the effects of radiation emitted under the foreseeable conditions of use and all marketed specimens must bear the protection-factor number corresponding to the spectral distribution curve of their transmission factor.

Glasses suitable for radiation sources of the same type must be classified in the ascending Order of their protection factors and the manufacturer's notes must indicate, in particular, the transmission curves which make it possible to select the most appropriate PPE, bearing in mind such inherent factors of the effective conditions of use as well as distance to source and the spectral distribution of the energy radiated at that distance.

The relevant protection-factor number must be marked on all specimens of filtering glasses by the manufacturer.

3.9.2. *Ionising radiation*

3.9.2.1. Protection against external radioactive contamination

PPE constituent materials and other components designed to protect all or part of the body against radioactive dust, gases, liquids or mixtures thereof must be so chosen or designed and incorporated as to ensure that this equipment effectively prevents the penetration of the contaminants under the foreseeable conditions of use.

Depending on the nature or condition of these contaminants, the necessary leak-tightness can be provided by the impermeability of the protective integument and/or by any other appropriate means, such as ventilation and pressurisation systems designed to prevent the back-scattering of these contaminants.

Any decontamination measures to which PPE is subject must not prejudice its possible re-use during the foreseeable useful life of these classes of equipment.

3.9.2.2. Limited protection against external irradiation

PPE intended to provide complete user protection against external irradiation or, failing this, adequate attenuation thereof, must be designed to counter only weak electron (e.g. beta) or weak photon (e.g. X, gamma) radiation.

The constituent materials and other components of these PPE classes must be so chosen or designed and incorporated as to provide the degree of user protection required by the foreseeable conditions of use without leading to an increase in exposure time as a result of the impedance of user gestures, posture or movement (see paragraph 1.3.2).

PPE must bear a mark indicating the type and thickness of the constituent material(s) suitable for the foreseeable conditions of use.

3.10. **Protection against dangerous substance and infectious agents**

3.10.1. *Respiratory protection*

PPE intended for the protection of the respiratory tract must make it possible to supply the user with breathable air when the latter is exposed to a polluted atmosphere and/or an atmosphere having inadequate oxygen concentration.

The breathable air supplied to the user by the PPE must be obtained by appropriate means, for example after filtration of the polluted air through the protective device or appliance or by a piped supply from an unpolluted source.

The constituent materials and other components of these PPE classes must be so chosen or designed and incorporated as to ensure appropriate user respiration and respiratory hygiene for the period of wear concerned under the foreseeable conditions of use.

The leak-tightness of the facepiece and the pressure drop on inspiration and, in the case of the filtering devices, purification capacity must be such as to keep contaminant penetration from a polluted atmosphere low enough not to be prejudicial to the health or hygiene of the user.

The PPE must bear the manufacturer's identification mark and details of the specific characteristics of that type of equipment which, in conjunction with the instructions for use, will enable a trained and qualified user to employ the PPE correctly.

The manufacturer's notes must also in the case of filtering devices, indicate the deadline for the storage of filters as new and kept in their original packaging.

3.10.2. *Protection against cutaneous and ocular contact*

PPE intended to prevent the surface contact of all or part of the body with dangerous substances and infectious agents must be capable of preventing the penetration or diffusion of such substances through the protective integument under the foreseeable conditions of use for which the PPE is placed on the market.

To this end, the constituent materials and other components of these PPE classes must be so chosen, or designed and incorporated as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leak-tightness necessitating restriction of the period of wear.

Where, by virtue of their nature and the foreseeable conditions of their use, certain dangerous substances or infectious agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of efficiency. PPE which is considered to be in conformity with the test specifications must bear a mark indicating, in particular, the names or, failing this, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's notes must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.

3.11. **Safety devices for diving equipment**

1. Breathing equipment

The breathing equipment must make it possible to supply the user with a breathable gaseous mixture, under foreseeable conditions of use and taking account in particular of the maximum depth of immersion.

2. Where the foreseeable conditions of use so require, the equipment must comprise:

- a suit which protects the user against the pressure resulting from the depth of immersion (see paragraph 3.2) and/or against cold (see paragraph 3.7);

- an alarm designed to give the user prompt warning of an approaching failure in the supply of breathable gaseous mixture (see paragraph 2.8);

- a life-saving suit enabling the user to return to the surface (see paragraph 3.4.1).

SCHEDULE 3

ANNEX III OF THE DIRECTIVE

TECHNICAL DOCUMENTATION SUPPLIED BY THE MANUFACTURER

The documentation referred to in paragraph 8.1 of the Order must comprise all relevant data on the means used by the manufacturer to ensure that a PPE complies with the basic requirements relating to it.

In the case of PPE models referred to in paragraph 8.2 of the Order, the documentation must comprise in particular:

1. the manufacturer's technical file consisting of:

(a) overall and detailed plans of the PPE accompanied, where appropriate, by calculation notes and the results of prototype tests in so far as necessary for the verification of compliance with the basic requirements;

(b) an exhaustive list of the basic safety requirements and of the harmonised standards or other technical specifications referred to in paragraph 5.3 and in paragraph 6 of the Order, taken into account in the design of the model;

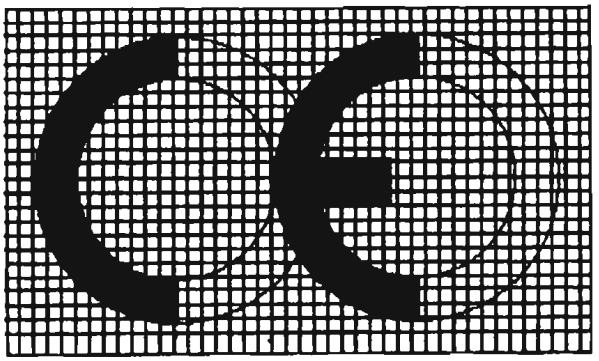
2. a description of the control and test facilities to be used in the manufacturer's plant to check compliance of production of PPE with the harmonised standards or other technical specifications and to maintain quality level;

3. a copy of the information notice referred to in paragraph 1.4 of Schedule 2 of the Order.

SCHEDULE 4

ANNEX IV OF THE DIRECTIVE

The CE conformity marking shall consist of the initials "CE" taking the following form:



If the CE marking is reduced or enlarged, the proportions given in the above graduated drawing must be respected.

The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5mm. This minimum dimension may be reduced for small-scale PPE.

SCHEDULE 5

ANNEX VI OF THE DIRECTIVE

MODEL DECLARATION OF CONFORMITY

The manufacturer or his authorised representative as recognised by the Malta Standardisation Authority[1]:

.....

declares that the new PPE described hereafter [2]:

.....

is in conformity with the provisions of Council Directive 89/686/EEC and, where such is the case, with the National Standard transposing the Harmonised Standard No.....(for the PPE referred to in Article 8 (3))

is identical to the PPE which is the subject of EC certificate of conformity No.....issued by[3] [4]:

.....

.....

is subject to the procedure set out in Article 11 point A or point B [4] of Council Directive 89/686/EEC under the supervision of the notified body[3]:

.....

Done at....., on.....

.....

Signature [5]

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[1] Business name and full address; the authorised representative as recognised by the Malta Standardisation Authority must also give the business name and address of the manufacturer.

[2] Description of the PPE (make, type, serial number, etc.).

[3] Name and address of the approved body.

[4] Delete whichever is inapplicable.

[5] Name and position of the person empowered to sign on behalf of the manufacturer or his authorised representative as recognised by the Malta Standardisation Authority.