

Manual for ITC's clients

from the area of conformity assessment of personal protective equipment pursuant to Council Directive 89/686/EEC and Czech Republic's Government Order No. 21/2003, Collection of Laws

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Approved by:

Dipl. Ing. Pavel Vaněk
Director of Certification Division

1. Introduction

The present Manual aims at facilitating customers of the Institute for Testing and Certification, a.s. (hereinafter referred to as only „ITC“) to prepare documents necessary for conformity assessment of personal protective equipment (hereinafter referred to as only „PPE“) and providing them with the essential information about their rights and obligations in placing PPE on the EU market.

ITC is a legal entity authorized to perform activities in conformity assessment of PPE placed on the markets of member states of the European Union and countries of the European Free Trade Association and notified for this activity by the European Commission as Notified Body No. 1023 (hereinafter referred to as only „NB 1023“).

Technical requirements for PPE and obligations of persons introducing PPE into the market of the European Union are laid down by the European Directive 89/686/EEC as amended by Council Directives 93/687/EEC, 93/95/EEC and the Directive of the European Parliament and the Council 96/58/EEC. In compliance with legislation of the European Union this Directive is implemented into the Czech legislation in the form of a *Czech Republic's Government Order No. 21/2003, Collection of Laws, which lays down technical requirements for PPE* (hereinafter referred to as only „GO 21“).

Practically it means that by meeting the requirements laid down by the GO 21 also requirements of the above directive are met at the same time. The product whose conformity with these requirements has been assessed by an authorized representative in co-operation with NB 1023 (ITC) may be introduced into the market of all EU and EFTA member states without any further restrictions and measures taken.

2. Definitions

2.1. Basic terms

- **personal protective equipment** shall mean any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards (see Section 1, Subsection 2 of the GO 21). PPE are subject to obligation of conformity assessment and affixing CE conformity marking prior to placing on the EU and EFTA markets. An exhaustive list of personal protection equipment classes not covered by the GO 21 is given in Annex 1 to this Order. Specifically, the products which the Directive does not apply to are as follows:
 1. PPE designed and manufactured specifically for use by the armed forces or in the maintenance of law and order (helmets, shields, etc.).
 2. 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 single-track and double-track vehicles.
- **European CE conformity marking** shall mean a marking placed on a product or its package by which the manufacturer confirms conformity of its properties with requirements of the appropriate Directive and GO;
- **essential requirements** shall mean technical requirements for products the meeting of which is a prerequisite for a minimum sufficient safety of a product provided they are used in a usual and reasonably foreseeable manner. They are defined in the New

Approach Directives related to the given product area and implemented into national legislation of the EU member states. Meeting the essential requirements is a decisive aspect of all conformity assessment procedures. The most frequent method of demonstration of the conformity with the essential requirements is a demonstration of conformity with the harmonized standard related to the product;

- **harmonized Czech technical standard** shall mean a Czech technical standard which fully adopts requirements of the harmonized European standard. Meeting requirements of a harmonized Czech or European standard is considered within their scope as meeting appropriate essential requirements of the Directives and the Government Order related to a given product;
- **notified body** shall mean a body authorised to defined activities in conformity assessment of products specified by a national authority (in case of the Czech Republic by Úřad pro technickou normalizaci, metrologii a státní zkušebnictví – ÚNMZ /Office for Standards, Metrology and Testing/) and notified to European Commission bodies and to all EU member states as a body authorised to carry out activities in conformity assessment of products for which it received the notification. Decisions and documents issued by all notified bodies (NB) are equal and valid in the entire EU;
- **conformity assessment procedure** shall mean a method defined by a directive or a GO by which the manufacturer demonstrates conformity of the product properties with essential requirements, usually with participation of a notified body;
- **EC type-examination** shall mean the procedure whereby a notified body ascertains whether a sample of a PPE meets essential requirements and if so, it confirms this fact by drawing up an EC type-examination certificate.
- **notification scope** shall mean a specific definition of the range of products and conformity assessment procedures for which the given NB, based on a demonstration of a professional and technical competence, is notified and authorized to conduct its activities;
- **authorized representative** shall mean a person established in a member state of EU who is authorized in writing by the manufacturer to act on his behalf with respect to meeting requirements of appropriate directives (and implementation thereof into national legislations of the member states) placed on the manufacturer;
- **placing a product on the market** shall mean the first making available in return for payment or free of charge of a product, with a view to distribution and/or use on the European Community market, or when the right of ownership thereto is transferred for the first time, unless stipulated otherwise by a special Act.

2.2. Abbreviations used

ATL	Accredited testing laboratory
Directive	For the purposes of this Manual, New Approach Directive, which lays down technical requirements for a given product area
ITC	Institut pro testování a certifikaci, a.s (Institute for Testing and Certification, a.s.)
NB	notified body
NB 1023	Notified Body 1023 (this designation has been assigned to ITC by the European Commission)
GO	Government Order
GO 21	Czech Republic's Government Order No. 21/2003, Collection of Laws, setting out technical requirements for personal protective equipment
OSMT	Office for Standards, Metrology and Testing
Act 22	Act 22/1997, Collection of Laws, on technical requirements for products and on amending and complementing certain laws, as amended

3. Scope of ITC's notification

ITC's notification in the area of the Council Directive 89/686/EEC and GO 21 covers PPE classes as follows:

- 1) clothing
 - against liquid chemicals
 - for workers exposed to heat
 - for fire-fighters
 - for use in welding and allied processes
 - for users of chain saws
 - for use where there is a risk of entanglement with moving parts
 - having electrostatic properties
 - capable of signalling the user's presence visually (signalling clothing of high visibility)
- 2) aprons for use with hand knives
- 3) for protection of head
 - industrial protective helmets
 - industrial helmets protecting user's head during impact
 - impact protection helmets for young children
 - for eye protection
 - for hands protection
 - for feet protection.

The scope of the notification has been set out by the OSMT's Decision No. 16/1999. Based on the provision of Section 10 of the GO 21 the same scope also applies to notification of NB 1023.

4. Legislation

4.1. Act 22/1997, Collection of Laws, and GO 21/2003, Collection of Laws

The legislation framework for conformity assessment of specified products is formed by the Act 22/1997, Collection of Laws, on technical requirements for products and on amending and complementing certain laws, as amended. Personal protective equipment are specified products in the sense of Section 12, Subsection 1 of the Act 22. Technical requirements for PPE are contained at a general level in the law and made specific in Czech Republic's Government Order 21/2003, Collection of Laws, which implements requirements of the Directive 89/686/EEC as amended, into the Czech legislation.

4.2. Related regulations

This part lists, for customer's information, related legislation that must be taken into account in the process of conformity assessment of products placed on the market of EU and the Czech Republic. It includes notably the Public Health Protection Act and its implementing decrees and acts on liability for damage caused by a defective product:

Act 258/2000, Collection of Laws, on Public Health Protection and an amendment of some related acts, as amended

Act 59/1998, Collection of Laws, on liability for damage caused by a defective product, as amended

Act 102/2001, Collection of Laws, on general safety of products and on an amendment of some acts, as amended

5. Harmonized technical standards concerning conformity assessment of PPE safety

A list of harmonized technical standards related to the Directive 89/686/EEC and GO 21 is given in Annex 1. It must be emphasized that these harmonized standards do not still cover all risks associated with PPE safety. There is also PPE for which no specific harmonized standard has been issued.

6. PPE classification

Personal protective equipment represents a broad range of products which, with respect to risks against which they protect, are very miscellaneous. It would not be reasonable to place the same demanding requirements on assessment of a filter protecting against toxic substances, failure of which means a direct jeopardy of user's life, and on gardener's gloves. According to dependence on the extent of a potential hazard associated with the use of a product the PPE is divided into three groups (categories). Definitions of the categories in the government order are perhaps rather complicated but distinguishing between them is very important. The government order defines precisely two groups only.

Personal protective equipment of a simple design where the manufacturer or importer can assume that the user can himself/herself assess the level of protection provided against risks that can be safely identified by the user in good time. This group of products is designated as products of **category one**. It includes for instance PPE intended to protect the wearer against mechanical action the effects of which are superficial (e.g. gardening gloves), against temperatures up to 50 °C, influences of atmospheric agents not extreme in nature, minor impacts or sunlight (e.g. sun glasses).

Category three covers personal protective equipment intended to protect life or to protect against risks that may seriously and permanently harm the health, and where the manufacturer or importer may assume that the user will be unable to identify these dangers in good time. This category shall cover PPE for protection of respiratory system, protection against temperatures exceeding 100 °C or lower than –50 °C, all PPE for protection against fall, etc.

The remaining personal protective equipment that, by its character, does not comply with the definition of either category one or three, is covered by **category two**.

Inclusion of a personal protective equipment into the above categories is by law manufacturer's or importer's job. Of course, in case of doubts the categorization can be consulted with the appropriate notified body. However, the result of such a consultation is not binding. Neither consideration by Česká obchodní inspekce (Czech Trade Inspection), which conducts surveillance of how requirements of Act 22/1997, Collection of Laws, and respective government orders are met, are not decisive since in the event of disputes it is only the court that has the final and decisive word.

7. Conformity assessment procedures

For separate PPE categories the government order prescribes various conformity assessment procedures called as a rule “Modules” in the EU legislation.

In case of simple Category I personal protective equipment conformity assessment under conditions specified by the manufacturer or importer will suffice. The manufacturer or importer can request the accredited body to carry out the tests and evaluate their results but it is not mandatory. Notified Body (NB) does not conduct such evaluations.

In case of the Category II PPE the manufacturer or importer of such PPE will assure a conformity assessment of a sample of the personal protective equipment (EC type-examination) by a notified body prior to its placement on the market. The notified body

assesses conformity of the sample of the personal protective equipment with requirements of the government order and confirms that the sample of the personal protective equipment meets these requirements. In such case the authorized body will draw up an EC Type-Examination Certificate and hands it over to the manufacturer or importer.

The EC type-examination before placing the product on the market is necessary in case of the PPE of the Category III. Since the products are used at high risk situations the manufacturer or importer must also assure a continuous inspection of the products. At his discretion he may choose either verification of the product conformity with the certified type or assessment of production quality system.

A chart of the procedures that will apply in separate categories of personal protective equipment is shown in the following table. The table may simultaneously be used as an aid for the manufacturer in PPE categorization and deciding which of the alternative assessment procedures for Category III personal protective equipment to choose.

Table: A scheme of procedures for PPE conformity assessment

Manufacturer or importer will decide whether the PPE is of a simple design (see Section 3, Subsection 2 of the GO)			
Yes Category I PPE	No Category II or III PPE		
The manufacturer (importer) will compare properties of the PPE with essential requirements of the Annex 2 of the GO and collect the needed technical documentation according to Annex 3 of the GO	The manufacturer (importer) will collect the necessary technical documentation according to Annex 3 of the GO and present it to the authorized body together with the Application for Conformity Assessment.		
	The authorized body will carry out EC Type-Examination pursuant to Section 4 of the GO.		
	Manufacturer (importer) will decide whether the PPE is intended for protection of life and protection against risks that may seriously and permanently harm the health (see Section 3, Subsection 3 of the GO).		
	No Category II PPE	Yes Category III PPE	
		Manufacturer (importer) selects method of yearly check (inspection).	
	EC product quality control system (see Section 5 of the GO)	EC production quality assurance system through supervision (see Section 6 of the GO)	
Manufacturer (importer) will issue a Declaration of Conformity. He submits the documentation assembled by the above procedure to inspection bodies.			

If the manufacturer or importer chooses the EC product quality control system (Section 5 of the GO 21) he must ensure the homogeneity of production and select a notified body that will carry out random checks and tests of the manufactured PPE at intervals shorter than one year.

If the manufacturer or importer selects the EC production quality assurance system through supervision (see Section 6 of the GO 21) he must have the system already implemented or he must implement it. The notified body will verify the production quality system and ascertain, through a supervision, whether the manufacturer maintains the system in the state in which it was verified.

8. Procedure for conformity assessment of PPE by NB 1023 according to Section 4 of the GO 21

This section describes thoroughly steps that the manufacturer, his authorized representative or the importer importing the PPE into the European Union must take in assessing conformity of the PPE. Should neither the manufacturer nor his authorized representative or importer be established in the European Union the responsibility for the conformity assessment of the PPE before supervision bodies shall be assumed by the person that was the last to place the product on the market.

For an easier distinction the activities of a person requesting the Notified Body 1023 (ITC) for a conformity assessment (the client) are described in a common typeface while responses and activities of NB 1023 are graphically differentiated by italics.

8.1.1. Application

The PPE manufacturer or its authorized representative or the importer of the PPE into the European Union (hereinafter referred to as “client”) lodges an application for an EC type-examination with the Notified Body 1023 using a form, which constitutes Annex 2 to this Manual. The client shall deliver the completed form personally or by mail to one of the contact persons shown below:

- a) Dipl. Ing. Elena Tomanová
(an expert for conformity assessment of PPE – body protection, eyes protection - in compliance with GO 21)
Institut pro testování a certifikaci, a.s.
třída Tomáše Bati 299
764 21 Zlín
Czech Republic
tel. (+420) 577 601 268, fax. (+420) 577 601 702, e-mail: etomanova@itczlin.cz

- b) Dipl. Ing. Miroslava Dostálová
(an expert for conformity assessment of PPE – head protection, hands protection, feet protection - in compliance with GO 21)
Institut pro testování a certifikaci, a.s.
třída Tomáše Bati 299
764 21 Zlín
Czech Republic
tel. (+420) 577 601 274, fax. (+420) 577 601 702, e-mail: mdostalova@itczlin.cz

- c) Jitka Fusková (secretariat of the Certification Division Manager)
Institut pro testování a certifikaci, a.s.
třída Tomáše Bati 299
764 21 Zlín
Czech Republic
tel. (+420) 577 601 623, fax. (+420) 577 104 855, e-mail: jfuskova@itczlin.cz

The application form can also be obtained by downloading the appropriate file from ITC's web site (home page www.itczlin.cz gradually using menu ENTER>Notified Body>Personal Protective Equipment >Application/) or at the request from the above contact persons who will send it by fax or e-mail. The client may send the application to ITC using also his/her own form on condition that the client's form contains all the data specified in the ITC's official application form.

Already at this stage it is advisable to supply with the application also samples and technical documentation as required by the Annex 3 of the GO 21. The documentation must contain all important data on the means used by the manufacturer to ensure conformity of the PPE with the essential requirements related to it, particularly:

1. a technical documents file (supplied by the manufacturer) comprising:
 - a) overall and detailed drawings of the PPE completed, if needed, with calculations and test results of the prototype in the extent necessary for verification of conformity with the essential requirements;
 - b) a complete list of essential requirements for safety and of harmonized standards or other technical specifications that were considered in designing the model;
2. a description of checking and testing equipment used at the manufacturer's plant for checking conformity of the PPE manufacture with harmonized standards or other technical specifications and for maintaining the quality level.
3. a copy of a notice (instructions) given in Section 1.4 of Annex 2 to the GO 21. These instructions (information supplied by the manufacturer) must contain all important information on:
 - a) storage, use, cleaning, maintenance, setting-up and disinfection. The cleaning, maintenance and disinfectant products recommended by the manufacturer must have no adverse effect on PPE or user when applied in accordance with the relevant instructions;
 - b) performed efficiency of the PPE in question, as stated during the tests checking the levels or classes of protection;
 - c) suitable PPE accessories and the characteristics of appropriate spare parts;
 - d) the classes of protection appropriate to different levels of risk and to the corresponding limits of use;
 - e) the obsolescence deadline or period of obsolescence of PPE or of its certain components;
 - f) the type of packaging suitable for transport;
 - g) the significance of all markings;
 - h) legal regulations if applied;
 - i) identification data of the notified body (NB number, name and address of its headquarters) in case of an application for surveillance or inspection of Category III PPE where the EC type-examination was carried out by other notified body.

The notice must be precise and comprehensible and must be drawn up at least in the official language or languages of the Member States of the European Union for which the PPE is intended. For placement of the product on the Czech market the notice must be in the Czech language, for placing on foreign markets in English and in the language of the country of destination.

The application and the documentation presented must be in either Czech or English. Use of other official languages of the European Union is possible only when agreed with the above expert. Instructions shown on the PPE or its package must be given at least in the language of the member state of the European Union, in the territory of which the PPE will be placed on the market. The instructions can be multilingual ones.

Filling in of the application form can be consulted, in case of an ambiguity, with the expert at the above contact addresses.

Neither the Directive 89/686/EEC nor the Act 22 allows the manufacturer or his authorized representative to lodge the application for EC type-examination of the same PPE with additional notified bodies.

8.1.2. Application review

The notified body is obliged under the law to respond to client's request for a service concerning conformity assessment within 20 days at the latest. The certification worker of NB 1023 (ITC) will register the application and review at this stage correctness and completeness of the application data or correctness of selection and number of samples supplied.

Should the application or the documentation be incomplete, the certification worker will specify in writing (by letter, e-mail, fax) the missing items and request their completion.

8.1.3. Draft of conformity assessment contract

NB 1023 will make a price proposal including price of the necessary tests as well as price of other certification activities and will elaborate a draft of the contract. Secretariat of the Notified Body will send the draft of the contract signed by an NB 1023 representative or his deputy to the applicant for approval and signing by a person authorized to act on his/her behalf. An annex to the contract is the present Manual for Clients. The NB 1023 will send the applicant simultaneously with the contract also the invoice for payment of an advance, unless agreed exceptionally otherwise.

The expert of NB 1023 will discuss client's comments, if any, on the wording of the draft contract with the director of the Certification Division. Based on acceptable comments a definitive wording of the contract draft will be elaborated. The NB 1023 representative will sign the contract draft and the secretariat will send it to the applicant for consent.

Should the applicant's comments be unacceptable and personal negotiation is not successful the contract will not be concluded and the NB 1023 secretariat will notify the applicant thereof in writing.

Continuation of the EC type-examination process, particularly start of the tests and assessment, is subject to applicant's consent to the price proposal, content of the contract and this Manual. The company will express its consent by signing the draft contract and paying the advance invoices. A necessary prerequisite for starting the activity is also supply of a sufficient quantity of samples.

8.1.4. Sampling

Together with the application the client is obliged, in compliance with the GO 21, to supply also a sample of the PPE. Exceptionally, when agreed with the contact persons, the samples can be provided also additionally; however, this will extend the period of time necessary to carry out the service of EC type-examination.

The samples of the PPE must represent the type intended for EC examination. The same „type“ may include several versions (models) of the product provided the differences between the versions affect neither safety level, quality characteristics nor the intended use of the product. PPE of the same type must be particularly manufactured from the same materials using identical technology and must be based on identical design characteristics. Assessment of the effect of deviations of various versions on safety and quality levels and on intended use of a given product is the exclusive right of NB 1023, which will take a final decision on the possibility of considering more product versions for a single type in the process of application acceptance and review of the technical documentation.

As a rule, the samples for type-examination are taken by the applicant according to requested written or telephone instructions provided by the responsible worker of NB 1023.

However, the client can ask the ITC's certification personnel for this service, which will be provided under usual commercial terms.

8.1.5. EC type-examination

After meeting all prerequisites referred to in Section 7.1.3., NB 1023 shall examine all the documents submitted by the applicant.

NB assures appropriate assessments and necessary tests of the PPE samples in its own laboratories or, exceptionally, in contractual accredited laboratories approved by OSMT. Results of the tests and assessment of the documentation will be compiled by the certification worker in a Final Report containing description of the PPE, description of the method utilized for type-examination, a list of documents issued by ITC or other entities, and unambiguous conclusions on conformity of the type with the essential requirements of the Directive 89/686/EEC and GO 21.

If the conclusions are positive, NB 1023 will draw up an EC Type-Examination Certificate, an integral part of which is the appropriate Final Report, and hands it over to the applicant under the conditions laid down in the Conformity Assessment Contract.

NB 1023 will publish the issuance of the EC Type-Examination Certificate in the internet database, which it administers on its publicly accessible pages at www.itczlin.cz.

If the EC type-examination demonstrates that the product fails to meet the essential requirements, the Notified Body NB 1023 will refuse to draw up the EC Type-Examination Certificate and will inform the applicant in writing about the reasons which led it to this decision.

In case of negative results the client may ask for a repeated EC type-examination of the product in question only after modifying the product in a manner assuring its conformity with essential requirements.

Such a request is considered from both technical and economic viewpoints for a new application based on which the entire procedure is repeated.

NB 1023 archives the documentation related to the EC type-examination for a period of 15 years.

8.1.6. Rules for recognition of results from the documentation submitted by the applicant

Recognition of the results obtained by other laboratories and presented in the documentation depends solely on the decision of the Notified Body NB 1023, which in no case disclaims its responsibility for the appropriate aspect of safety of the type of the PPE examined.

As a rule, results given in test reports by accredited laboratories are recognized on condition that no more than 3 years have elapsed from the date of issue of the report.

In principle, results of tests carried out by manufacturer's or non-accredited laboratories are not recognized. Tests performed on unique testing equipment not commonly accessible may constitute an exception. In such cases NB 1023 prefers conducting the tests under the supervision of its own experts.

In case of recognition of results obtained by accredited laboratories other than those of NB 1023 the Notified Body NB 1023 makes usually a repeated check of some characteristic by performing tests in its own laboratories.

8.1.7. Validity of EC Type-Examination Certificate

Geographical validity of the EC Type-Examination Certificate is given by the number of countries that implemented the Directive 89/686/EEC into their legislation and allow placement of CE-marked products on their own markets. They are primarily member states of EU and EFTA or candidate countries that have concluded with EU the PECA agreement (Protocol on Conformity Assessment and the Acceptance of Industrial Products) containing a sector annex aimed at mutual recognition of results of conformity assessment of PPE.

From the time point of view the validity of the EC Type-Examination Certificate is limited to 5 years

If an essential change in the harmonized standards or relevant directives used has been made the Notified Body NB 1023, based on manufacturer's request, will consider whether the design of the PPE in question must be modified or the product characteristics affected by the change retested or if the existing Certificate remains in force without any change of the product. NB 1023 shall notify the manufacturer of the result of the examination in writing.

If a change in the technological conditions of the manufacture was made during the life of the EC Type-Examination Certificate the Certificate holder may inquire the above contact personnel of NB 1023. The ITC's expert considers whether the reported changes in the manufacturing process can result in changes in the safety characteristics of the certified type of the PPE and advises the Certificate holder in writing whether a new EC type-examination is necessary or not.

8.2. EC product quality control system pursuant to Section 5 of the GO 21 (it will be applied to Category III PPE only)

EC quality control system for the product is a procedure whereby

- a) the manufacturer shall take all steps necessary to ensure that the manufacturing process, including the final inspection and tests of PPE, ensures the homogeneity of production and the conformity of PPE with the type described in the certificate and with the relevant basic requirements,
- b) a notified body chosen by the manufacturer shall carry out the necessary checks of PPE at random, normally at intervals not exceeding one year.

At an interval not exceeding one year from issue of the EC Type-Examination Certificate or from the date of the last check, the client shall lodge with the Notified Body NB 1023 an application for conducting random checks in the framework of the **EC product quality control system** using a form given in the Annex 3 of the present Manual. The client shall deliver the completed form either in person or by mail to one of the contact persons given in Section 7.1.1.

The procedure for review of the application and the procedure for drafting the contract are identical with those already described in Sections 7.1.2 and 7.1.3 of this Manual.

Continuation of the checking process, particularly taking of the test samples, start of the tests and assessment, are subject to applicant's consent to the price proposal, content of the contract and this Manual. The company will express its consent by signing the draft contract and paying the advance invoices.

Responsible workers of NB 1023 shall take the samples to be used for the check directly at the client's premises at an extent necessary for carrying out the test needed to prove conformity of the product with the essential requirements of the GO 21 and to prove conformity of the product sampled with the type described in the appropriate EC Type-Examination Certificate.

NB shall ensure the appropriate assessments and the necessary tests of the PPE samples in its own or exceptionally in contractual laboratories approved by OSMT

Results of the tests and assessment of the documentation will be compiled by the certification worker in a Test Report containing description of the PPE, description of the method utilized for type-examination, a list of documents issued by ITC or other entities and unambiguous conclusions on conformity of the product tested with the type described in the EC Type-Examination Certificate. Subsequently, the Test Report shall be sent to the applicant under the conditions stipulated in the Contract.

If the Report concludes that the product examined fails to conform to the type described in the Certificate or does not meet the essential requirements of the GO 21, the Notified Body shall take measures adequate to the gravity of the stated faults and inform thereof both the client and OSMT.

8.3. EC production quality assurance system through supervision pursuant to Section 6 of the GO 21 (applies to Category III PPE only)

System for ensuring EC quality of production through supervision is a procedure whereby the Notified Body NB 1023 approves the manufacturer's quality control system and through monitoring ascertains whether the manufacturer keeps the obligations arising from the approved quality control system.

8.3.1. Application

The manufacturer shall submit an application for the approval of quality control system to the NB 1023. The application must include:

- a) all the information relating to the PPE concerned,
- b) documentation on the quality control system and
- c) the manufacturer's commitment to fulfil the obligations arising from the quality control system and to maintain its adequacy and efficiency.

The procedure for review of the application and the procedure for drafting the contract are identical with those already described in Sections 7.1.2 and 7.1.3 of this Manual.

8.3.2. Examination of PPE by the manufacturer

Under the quality control system the manufacturer examines each PPE to assess its conformity to the relevant essential requirements. The documentation on the quality control system must in particular include a description of:

- a) quality objectives, organization chart, responsibilities of the management and powers and responsibilities of the management with respect to product quality,
- b) checks and tests that must be carried out after manufacture and
- c) means enabling supervision of the efficient operation of the quality control system.

8.3.3. Assessment of the quality control system by the Notified Body

The Notified Body NB 1023 shall

- a) *assess the quality control system in order to determine whether it satisfies the provisions referred to in Subsection 7.3.2. It shall assume that quality systems applying the relevant standard satisfy those provisions.*
- b) *make, in carrying out the audit, all necessary objective evaluations of the components of the quality control system and check in particular whether the system ensures conformity of the PPE manufactured with the type described in the certificate, and*
- c) *communicate the decision including the conclusions of the check and the reasoned assessment to the manufacturer.*

The manufacturer shall inform the Notified Body NB 1023 which approved the quality control system in writing (by a letter, e-mail or fax) of any plan to alter the quality control system.

The Notified Body 1023 shall examine the proposed changes and decide whether the altered quality control system satisfies the relevant provisions. It shall communicate its decision to the manufacturer. The communication shall include the conclusions of the check and the reasoned assessment decision.

8.3.4. Supervision of the production control system

The supervision of the production quality control system operated by a manufacturer is a procedure the purpose of which is to ensure that the manufacturer correctly fulfils the obligations arising from the approved quality control system.

Within this procedure

- a) the manufacturer shall allow the authorized personnel of the Notified Body NB 1023 to have access, for purposes of supervision, to PPE inspection, testing and storage sites and shall provide the body with all requisite information, in particular:
 - 1) documentation on the quality control system
 - 2) technical documentation
 - 3) quality control manuals,
- b) *NB 1023 shall periodically conduct audits (at intervals shorter than one year) to ensure that the manufacturer is maintaining and applying the approved quality control system. It shall provide the manufacturer with a copy of the Audit Report,*
- c) *the Notified Body may also make unannounced visits to the manufacturer. In case of such visits the Notified Body shall provide the manufacturer with a report of the visit and, if appropriate, also with an audit report,*

9. EC Declaration of conformity

Every manufacturer or importer of personal protective equipment must draw up an EC Declaration of conformity irrespective of the PPE category. This Declaration is available to users of the PPE as a guarantee that the relevant product meets essential requirements of the Government Order.

The Declaration of conformity shall be drawn up on the basis of technical documentation, i.e. drawings, calculations, tests and observations necessary for verification of and compliance with the essential requirements.

The technical documentation for PPE of the Categories II and III must include also EC Type-Examination Certificate. In case of the Category III PPE also a checking method must be established and resultant reports on regular yearly inspections conducted by an authorized body have to be available.

Validity of the EC Declaration of conformity is not limited. Only when changes that can affect properties of the personal protective equipment with respect to essential requirements are made a new Declaration must be drawn up. Of course, the technical documentation, based on which the Declaration is drawn up must be complete and systematically updated. For PPE of the Category III this means that also regular reports by the notified body on verification of the product conformity with the certified type or on assessment of the production quality system must be drawn up.

10. CE marking and other marking

The CE marking, the graphical form of which has been specified in the GO 291/2000, Collection of Laws, shall be affixed to each PPE so as to be visible, legible and indelible throughout the foreseeable useful life of that PPE. However, where this is not possible due to the character of the product, the CE marking may be affixed onto the product packaging. The individual parts of the CE marking must be essentially of the same height that must not be less than 5 mm. In PPE of small size these minimum dimensions need not be kept. PPE must not be provided with marks which could be confused with the CE marking.

In the event the NB is involved in the stage of production control (in case of Category III PPE), its identification number must be given in addition to the CE marking.

Any other marking may be affixed onto the PPE or its packaging provided that the visibility and legibility of the CE marking is not thereby reduced.

The CE marking on PPE signifies that the product satisfies the technical requirements laid down in all the legal regulations which apply to it and which constitute or enable this marking, and that the prescribed procedure was adhered to in assessing its conformity. This for instance means that for PPE incorporating electric drives or electronic elements, requirements not only of the GO 21 but also GO 18/2003, Collection of Laws, on electromagnetic compatibility (EMC) or, if appropriate, of the GO 1782003 on electric safety must be met.

But if one or several legal regulations allow, for a transitory period, the producer to choose the provisions he will observe, then the CE marking signifies the conformity only with those legal regulations which the producer used. In this case the documentation, notices or instructions, required by the mentioned legal regulations and attached to the relevant products, must state the relevant legal regulations of the European Communities or their provisions which the manufacturer used.

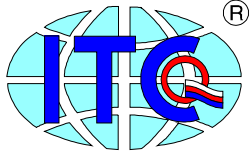
11. Possible extension of the service with other services provided by ITC

In addition to the notified services ITC offers other services including:

- check of completeness and correctness of the documentation of imported PPE;
- a “turnkey” elaboration of a specific documentation necessary for placing a product on the market;
- granting of a licence to use the certification mark “ITC Certified Quality” on products that meet not only essential safety requirements but have also above-average quality level. Detailed information and rules for granting the above mark can be obtained on www.itczlin.cz in the menu „O nás“ > „Certifikační značky“ > „ITC certifikovaná kvalita“ (“About us” > „Certification marks“ > „ITC Certified Quality“).

12. Conclusion

This Manual for clients of PPE conformity assessment is a comprehensive information source serving to ensure a smooth conformity assessment process. The Manual constitutes an annex to conformity assessment contracts since Section 7 of the Manual describes in detail the procedure to be taken by an applicant for EC type-examination and the procedure to be taken by the notified body NB 1023 (ITC) in provision of the service, i.e. conformity assessment.



INSTITUTE FOR TESTING AND CERTIFICATION, a. s.
Quality system certified according to EN ISO 9001:2000

Authorized Body 224 * Notified Body 1023 * Accredited Testing Laboratory * Accredited Calibration Laboratory * Accredited Certification Body

ANNEX 1

to

Manual for ITC's clients

from the area of conformity assessment of personal protective equipment
pursuant to Council Directive 89/686/EEC and Czech Republic's Government
Order No. 21/2003, Collection of Laws

List of harmonized EN standards to PPE Directive

Reference	Title of the Harmonised Standards	First publication (OJ)
EN 132:1998	Respiratory protective devices - Definitions of terms and pictograms	04.06.1999
EN 133:2001	Respiratory protective devices - Classification	10.08.2002
EN 134:1998	Respiratory protective devices - Nomenclature of components	13.06.1998
EN 135:1998	Respiratory protective devices - List of equivalent terms	04.06.1999
EN 136:1998	Respiratory protective devices - Full-face masks : requirements, testing, marking	13.06.1998
EN 137:1993	Respiratory protective devices - Self-contained open-circuit compressed-air breathing apparatus - requirements, testing, marking	23.12.1993
EN 138:1994	Respiratory protective devices - Fresh air hose breathing apparatus for use with full face mask, half mask or mouthpiece assembly - Requirements, testing, marking	16.12.1994
EN 139:1994	Respiratory protective devices - Compressed air line breathing apparatus for use with full face mask, half mask or mouthpiece assembly - Requirements, testing, marking	30.08.1995
EN 139/A1:1999	Respiratory protective devices - Compressed air line breathing apparatus for use with a full face mask, half mask or a mouthpiece assembly - Requirements, testing, marking - Amendment 1	05.11.1999
EN 140:1998	Respiratory protective devices - Half-masks and quarter-masks - Requirements, testing, marking	06.11.1998
EN 141:2000	Respiratory protective devices - Gas filters and combinets filters - Requirements, testing, marking	24.01.2001
EN 142:2002	Respiratory protective devices - Mouthpieces assemblies - Requirements, testing, marking	10.04.2003
EN 143:2000	Respiratory protective devices - Particle filters - Requirements, testing, marking	24.01.2001
EN 144-1:2000	Respiratory protective devices - Gas cylinder valves - Part 1: Thread connection for insert connector	24.01.2001
EN 144-1/A1:2003	Respiratory protective devices - Gas cylinder valves - Part 1: Thread connections for insert connector - Amendment 1	21.02.2004
EN 144-2:1998	Respiratory protective devices - Gas cylinder valves - Part 2: Outlet connections	04.06.1999
EN 144-3:2003	Respiratory protective devices - Gas cylinder valves - Part 3: Outlet connections for diving gases Nitrox and oxygen	21.02.2004
EN 145:1997	Respiratory protective devices - Self-contained closed-circuit breathing apparatus compressed oxygen or compressed oxygen-nitrogen type - Requirements, testing, marking	19.02.1998

Reference	Title of the Harmonised Standards	First publication (OJ)
EN 145/A1:2000	Respiratory protective devices - Self-contained closed-circuit breathing apparatus compressed oxygen or compressed oxygen-nitrogen type - Requirements, testing, marking - Amendment 1	24.01.2001
EN 148-1:1999	Respiratory protective devices - Threads for facepieces - Part 1: Standard thread connection	04.06.1999
EN 148-2:1999	Respiratory protective devices - Threads for facepieces - Part 2: Centre thread connection	04.06.1999
EN 148-3:1999	Respiratory protective devices - Threads for facepieces - Part 3: Thread connection M 45 x 3	04.06.1999
EN 149:2001	Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking	21.12.2001
EN 165:1995	Personal eye-protection - Vocabulary	15.05.1996
EN 166:2001	Personal eye protection - Specifications	10.08.2002
EN 167:2001	Personal eye protection - Optical test methods	10.08.2002
EN 168:2001	Personal eye protection - Non-optical test methods	10.08.2002
EN 169:2002	Personal eye-protection - Filters for welding and related techniques - Transmittance requirements and recommended use	28.08.2003
EN 170:2002	Personal eye-protection - Ultraviolet filters -Transmittance requirements and recommended use	28.08.2003
EN 171:2002	Personal eye protection - Infrared filters - transmittance requirements and recommended use	10.04.2003
EN 172:1994	Personal eye protection - Sunglare filters for industrial use	15.05.1996
EN 172/A1:2000	Personal eye protection - Sunglare filters for industrial use - Amendment 1	04.07.2000
EN 172/A2 :2001	Personal eye protection - Sunglare filters for industrial use - Amendment 2	10.08.2002
EN 174/2001	Personal-eye protection - Ski goggles for downhill skiing	21.12.2001
EN 175:1997	Personal protection - Equipment for eye and face protection during welding and allied processes	19.02.1998
EN 207:1998	Personal eye-protection - Filters and eye-protectors against laser radiation (laser-eye protectors)	21.11.1998
EN 207/A1:2002	Personal eye-protection - Filters and eye-protectors against laser radiation (laser eyes-protectors) Amendment 1	28.08.2003

Reference	Title of the Harmonised Standards	First publication (OJ)
EN 208:1998	Personal eye-protection - Eye-protectors for adjustment work on lasers and laser systems (laser adjustment eye-protectors)	21.11.1998
EN 208/A1:2002	Personal eye-protection - Eye-protectors for adjustment work on lasers and laser systems (laser adjustment eye-protectors) Amendment 1	28.08.2003
EN 250:2000	Respiratory equipment - Open-circuit self-contained compressed air diving apparatus - Requirements, testing, marking	08.06.2000
EN 269:1994	Respiratory protective devices - Powered fresh air hose breathing apparatus incorporating a hood - Requirements, testing, marking	16.12.1994
EN 270:1994	Respiratory protective devices - Compressed air line breathing apparatus incorporating a hood - Requirements, testing, marking	30.08.1995
EN 270/A1:2000	Respiratory protective devices - Compressed air line breathing apparatus incorporating a hood - Requirements, testing, marking - Amendment 1	08.06.2000
EN 271:1995	Respiratory protective devices - Compressed air line or powered fresh air hose breathing apparatus incorporating a hood for use in abrasive blasting operations - Requirements, testing, marking	12.01.1996
EN 271/A1:2000	Respiratory protective devices - Compressed air line or powered fresh air hose breathing apparatus incorporating a hood for use in abrasive blasting operations - Requirements, testing, marking - Amendment 1	08.06.2000
EN 340:1993	Protective clothing - General requirements.	16.12.1994
EN 341:1992	Personal protective equipment against falls from a height - Descender devices	23.12.1993
EN 341/A1:1996	Personal protective equipment against falls from a height - Descender devices - Amendment 1	06.11.1998
EN 343:2003	Protective clothing - Protection against rain	21.02.2004
EN 344:1992	Requirements and test methods for safety, protective and occupational footwear for professional use	23.12.1993
EN 344/A1:1997	Requirements and test methods for safety, protective and occupational footwear for professional use - Amendment 1	19.02.1998
EN 344-2:1996	Safety, protective and occupational footwear for professional use - Part 2: Additional requirements and test methods	03.12.1996
EN 345:1992	Specification for safety footwear for professional use	23.12.1993
EN 345/A1:1997	Specification for safety footwear for professional use - Amendment 1	19.02.1998
EN 345-2:1996	Safety footwear for professional use - Part 2: Additional specifications	03.12.1996

Reference	Title of the Harmonised Standards	First publication (OJ)
EN 346:1992	Specification for protective footwear for professional use	23.12.1993
EN 346/A1:1997	Specification for protective footwear for professional use - Amendment 1	19.02.1998
EN 346-2:1996	Protective footwear for professional use - Part 2: Additional specifications	03.12.1996
EN 347:1992	Specification for occupational footwear for professional use	23.12.1993
EN 347/A1:1997	Specification for occupational footwear for professional use - Amendment 1	19.02.1998
EN 347-2:1996	Occupational footwear for professional use - Part 2: Additional specifications	14.06.1997
EN 348:1992	Protective clothing - Test method : determination of behaviour of materials on impact of small splashes of molten metal	23.12.1993
EN 352-1:2002	Hearing protectors - General requirements - Part 1: Ear muffs	28.08.2003
EN 352-2:2002	Hearing protectors - General requirements - Part 2: Ear-plugs	28.08.2003
EN 352-3:2002	Hearing protectors - General requirements - Part 3: Ear-muffs attached to an industrial safety helmet	28.08.2003
EN 352-4 :2001	Hearing protectors - Safety requirements and testing - Part 4: Level-dependent ear-muffs	10.08.2002
EN 352-5:2002	Hearing protectors - Safety requirements and testing - Part 5: Active noise reduction ear-muffs	28.08.2003
EN 352-6:2002	Hearing protectors - Safety requirements and testing - Part 6: Ear-muffs with electrical audio input	28.08.2003
EN 352-7:2002	Hearing protectors - Safety requirements and testing - Part 7: Level-dependent ear-plugs	28.08.2003
EN 353-1 :2002	Personal protective equipment against falls from a height - Part 1 : Guided type fall arresters including a rigid anchor line	28.08.2003
EN 353-2 :2002	Personal protective equipment against falls from a height - Part 2 : Guided type fall arresters including a flexible anchor line	28.08.2003
EN 354 :2002	Personal protective equipment against falls from a height - Lanyards	28.08.2003
EN 355 :2002	Personal protective equipment against falls from a height - Energy absorbers	28.08.2003
EN 358:1999	Personal protective equipment for work positioning and prevention of falls from a height - Belts for work positioning and restraint and work positioning lanyards	21.12.2001
EN 360:2002	Personal protective equipment against falls from a height - Retractable type fall arresters	28.08.2003
EN 361:2002	Personal protective equipment against falls from a height - Full body harnesses	28.08.2003

Reference	Title of the Harmonised Standards	First publication (OJ)
EN 362:1992	Personal equipment against falls from a height - Connectors	23.12.1993
EN 363:2002	Personal protective equipment against falls from a height - Fall arrest systems	28.08.2003
EN 364:1992	Personal equipment against falls from a height - Test methods	23.12.1993
EN 365:1992	Personal equipment against falls from a height - General requirements for instructions for use and for marking	23.12.1993
EN 367:1992	Protective clothing - Protection against heat and fire - Method of determining heat transmission on exposure to flame	23.12.1993
EN 368:1992	Protective clothing - Protection against liquid chemicals - Test method : resistance of materials to penetration by liquids	23.12.1993
EN 369:1993	Protective clothing - Protection against liquid chemicals - Test method : resistance of materials to permeation by liquids	23.12.1993
EN 371:1992	Respiratory protective devices - AX gas filters and combined filters against low-boiling point organic compounds - Requirements, testing, marking.	23.12.1993
EN 372:1992	Respiratory protective devices - SX gas filters and combined filters against specific named compounds - Requirements, testing, marking.	23.12.1993
EN 373:1993	Protective clothing - Assessment of resistance of materials to molten metal splash	23.12.1993
EN 374-1:1994	Protective gloves against chemicals and micro-organisms - Part 1: Terminology and performance requirements	16.12.1994
EN 374-2:1994	Protective gloves against chemicals and micro-organisms - Part 2: Determination of resistance to penetration	16.12.1994
EN 374-3:1994	Protective gloves against chemicals and micro-organisms - Part 3: Determination of resistance to permeation by chemicals.	16.12.1994
EN 379:1994	Specification for welding filters with switchable luminous transmittance and welding filters with dual luminous transmittance	16.12.1994
EN 379/A1:1998	Specification for welding filters with switchable luminous transmittance and welding filters with dual luminous transmittance - Amendment 1	06.11.1998
EN 381-1:1993	Protective clothing for users of hand-held chain saws - Part 1 : Test rig for testing resistance to cutting by a chainsaw	23.12.1993
EN 381-2:1995	Protective clothing for users of hand-held chain saws - Part 2 : Test methods for leg protectors	12.01.1996
EN 381-3:1996	Protective clothing for users of hand-held chain-saws - Part 3: Test methods for footwear	10.10.1996
EN 381-4:1999	Protective clothing for users of hand-held chainsaws - Part 4: Test methods for chainsaw protective gloves	16.03.2000

Reference	Title of the Harmonised Standards	First publication (OJ)
EN 381-5:1995	Protective clothing for users of hand-held chain saws - Part 5 : Requirements for leg protectors	12.01.1996
EN 381-7:1999	Protective clothing for users of hand-held chainsaws - Part 7: Requirements for chainsaw protective gloves	16.03.2000
EN 381-8:1997	Protective clothing for users of hand-held chain saws - Part 8 : Test methods for chain saw protective gaiters	18.10.1997
EN 381-9:1997	Protective clothing for users of hand-held chain saws - Part 9 : Requirements for chain saw protective gaiters	18.10.1997
EN 381-10:2002	Protective clothing for users of hand-held chainsaws - Part 10: Test method for upper body protectors	28.08.2003
EN 381-11:2002	Protective clothing for users of hand-held chainsaws - Part 11: Requirements for upper body protectors	28.08.2003
EN 388:1994	Protective gloves against mechanical risks	16.12.1994
EN 393:1993	Lif jackets and personal buoyancy aids Buoyancy aids - 50 N.	16.12.1994
EN 393/A1:1998	Lif jackets and personal buoyancy aids - Buoyancy aids - 50 N - Amendment 1	06.11.1998
EN 394:1993	Lif jackets and personal buoyancy aids Additional items	16.12.1994
EN 395:1993	Lif jackets and personal buoyancy aids - Lif jackets - 100 N	16.12.1994
EN 395/A1:1998	Lif jackets and personal buoyancy aids - Lif jackets - 100 N - Amendment 1	06.11.1998
EN 396:1993	Lif jackets and personal buoyancy aids - Lif jackets - 150 N	16.12.1994
EN 396/A1:1998	Lif jackets and personal buoyancy aids - Lif jackets - 150 N - Amendment 1	06.11.1998
EN 397:1995	Industrial safety helmets	12.01.1996
EN 397/A1:2000	Industrial safety helmets - Amendment 1	24.01.2001
EN 399:1993	Lif jackets and personal buoyancy aids - Lif jackets - 275 N	16.12.1994
EN 399/A1:1998	Lif jackets and personal buoyancy aids - Lif jackets - 275 N - Amendment 1	06.11.1998
EN 402:2003	Respiratory protective devices - Lung governed demand self-contained open-circuit compressed air breathing apparatus with full face mask or mouthpiece assembly for escape - Requirements, testing, marking	21.02.2004
EN 403:1993	Respiratory protective devices for self-rescue - Filtering devices with hood for self-rescue from fire - Requirements, testing, marking	23.12.1993
EN 404:1993	Respiratory protective devices for self-rescue - Filter self-rescuer - Requirements, testing, marking	16.12.1994

Reference	Title of the Harmonised Standards	First publication (OJ)
EN 405:2001	Respiratory protective devices - valved filtering half-masks to protect against gases or gases and particles - Requirements, testing, marking	10.08.2002
EN 407:1994	Protective gloves against thermal risks (Heat and/or fire)	16.12.1994
EN 420:1994	General requirements for gloves	16.12.1994
EN 421:1994	Protective gloves against ionising radiation and radioactive contamination	16.12.1994
EN 443:1997	Helmets for fire-fighters	19.02.1998
EN 458:1993	Hearing protectors - Recommendations for selection, use, care and maintenance - Guidance document	16.12.1994
EN 463:1994	Protective clothing for use against liquid chemicals - Test method : Determination of resistance to penetration by a jet of liquid (Jet test)	16.12.1994
EN 464:1994	Protective clothing for use against liquid and gaseous chemicals including aerosols and solid particles - Test method : Determination of leak-tightness of gas-tight suits (Internal pressure Test)	16.12.1994
EN 465:1995	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)	12.01.1996
EN 465/A1:1998	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) - Amendment 1	04.06.1999
EN 466:1995	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)	12.01.1996
EN 466/A1:1998	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) - Amendment 1	04.06.1999
EN 467:1995	Protective clothing - Protection against liquid chemicals - Performance requirements for garments providing protection to parts of the body	14.06.1997
EN 467/A1:1998	Protective clothing - Protection against liquid chemicals - Performance requirements for garments providing protection to parts of the body - Amendment 1	04.06.1999
EN 468:1994	Protective clothing for use against liquid chemicals - Test method : Determination of resistance to penetration by spray (Spray test)	16.12.1994

Reference	Title of the Harmonised Standards	First publication (OJ)
EN 469:1995	Protective clothing for fire-fighters - Requirements and test methods for protective clothing for firefighting	15.05.1996
EN 470-1:1995	Protective clothing for use in welding and allied processes - Part 1 : General requirements	12.01.1996
EN 470-1/A1:1998	Protective clothing for use in welding and allied processes - Part 1 : General requirements - Amendment 1	13.06.1998
EN 471:1994	High-visibility warning clothing	16.12.1994
EN 510:1993	Specification for protective clothing for use where there is a risk of entanglement with moving parts	16.12.1994
EN 511:1994	Protective gloves against cold	16.03.2000
EN 530:1994	Abrasion resistance of protective clothing material - Test methods.	30.08.1995
EN 531:1995	Protective clothing for industrial workers exposed to heat (excluding firefighters' and welders' clothing)	06.11.1998
EN 531/A1:1998	Protective clothing for workers exposed to heat - Amendment 1	04.06.1999
EN 533:1997	Protective clothing - Protection against heat and flame - Limited flame spread materials and material assemblies	14.06.1997
EN 564 :1997	Mountaineering equipment - Accessory cord - Safety requirements and test methods	10.08.2002
EN 565 :1997	Mountaineering equipment - Tape - Safety requirements and test methods	10.08.2002
EN 566 :1997	Mountaineering equipment - Slings - Safety requirements and test methods	10.08.2002
EN 567 :1997	Mountaineering equipment - Rope clamps - Safety requirements and test methods	10.08.2002
EN 568:1997	Mountaineering equipment - Ice anchors - Safety requirements and test methods	14.06.1997
EN 569 :1997	Mountaineering equipment - Pitons - Safety requirements and test methods	10.08.2002
EN 659:2003	Protective gloves for fire-fighters	21.02.2004
EN 702:1994	Protective clothing - Protection against heat and flame - Test method : Determination of the contact heat transmission through protective clothing or its materials	12.01.1996
EN 795:1996	Protection against falls from a height - Anchor devices - Requirements and testing	12.02.2000
EN 795/A1:2000	Protection against falls from a height - Anchor devices - Requirements and testing - Amendment 1	24.01.2001
EN 812:1997	Industrial bump caps	19.02.1998

Reference	Title of the Harmonised Standards	First publication (OJ)
EN 812/A1 :2001	Industrial bump caps - Amendment 1	10.08.2002
EN 813:1997	Personal protective equipment for prevention of falls from a height - Sit harnesses	14.06.1997
EN 863:1995	Protective clothing - Mechanical properties - Test method : Puncture Resistance	15.05.1996
EN 892:1996	Mountaineering equipment - Dynamic mountaineering ropes - Safety requirements and test methods	14.06.1997
EN 893 :1999	Mountaineering equipment - Crampons - Safety requirements and test methods	10.08.2002
EN 943-1 :2002	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	28.08.2003
EN 943-2 :2002	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)	10.08.2002
EN 958:1996	Mountaineering equipment - Energy absorbing systems for use in klettersteig (via ferrata) climbing - Safety requirements and test methods	14.06.1997
EN 960:1994	Headforms for use in the testing of protective helmets	15.05.1996
EN 960/A1:1998	Headforms for use in the testing of protective helmets - Amendment 1	06.11.1998
EN 966:1996	Helmets for airborne sports	10.10.1996
EN 966/A1:2000	Helmets for airborne sports - Amendment 1	04.07.2000
EN 967:1996	Head protectors for ice hockey players	14.06.1997
EN 1073-1:1998	Protective clothing against radioactive contamination - Part 1: Requirements and test methods for ventilated protective clothing against particulate radioactive contamination	06.11.1998
EN 1073-2:2002	Protective clothing against radioactive contamination - Part 2: Requirements and test methods for non-ventilated protective clothing against particulate radioactive contamination	28.08.2003
EN 1077:1996	Helmets for alpine skiers	10.10.1996
EN 1078:1997	Helmets for pedal cyclists and for users of skateboards and roller skates	14.06.1997
EN 1080:1997	Impact protection helmets for young children	14.06.1997
EN 1080/A1:2002	Impact protection helmets for young children - Amendment 1	28.08.2003
EN 1082-1:1996	Protective clothing - Gloves and arm guards protection against cuts and stabs by hand knives - Part 1: Chain mail gloves and arm guards	14.06.1997
EN 1082-2:2000	Protective clothing - Gloves and arm guards protection against cuts and stabs by hand knives - Part 2: Chain mail gloves and arm guards	21.12.2001
EN 1082-3:2000	Protective clothing - Gloves and arm guards protecting against cuts and stabs by hand knives - Part 3: Impact cut test for fabric, leather and other materials	21.12.2001

Reference	Title of the Harmonised Standards	First publication (OJ)
EN 1095:1998	Deck safety harness and safety line for use on recreational craft - Safety requirements and test methods	06.11.1998
EN 1146:1997	Respiratory protective devices for self-rescue - Self-contained open-circuit compressed air breathing apparatus incorporating a hood (compressed air escape apparatus with hood) - Requirements, testing, marking	14.06.1997
EN 1146/A1:1998	Respiratory protective devices - Self-contained open-circuit compressed air breathing apparatus incorporating a hood (compressed air escape apparatus with hood) - Requirements, testing, marking - Amendment 1	04.06.1999
EN 1146/A2:1999	Respiratory protective devices - Self-contained open-circuit compressed air breathing apparatus incorporating a hood (compressed air escape apparatus with hood) - Requirements, testing, marking - Amendment 2	16.03.2000
EN 1146/A3 :2001	Respiratory protective devices - Self-contained open-circuit compressed air breathing apparatus incorporating a hood (compressed air escape apparatus with hood) - Requirements, testing, marking - Amendment 3	10.08.2002
EN 1149-1:1995	Protective clothing - Electrostatic properties - Part 1: Surface resistivity (Test methods and requirements)	10.10.1996
EN 1149-2:1997	Protective clothing - Electrostatic properties - Part 2: Test method for measurement of the electrical resistance through a material (vertical resistance)	19.02.1998
EN 1150:1999	Protective clothing - Visibility clothing for non-professional use - Test methods and requirements	04.06.1999
EN 1384:1996	Helmets for equestrian activities	14.06.1997
EN 1384/A1 :2001	Helmets for equestrian activities - Amendment 1	10.08.2002
EN 1385:1997	Helmets for canoeing and white water sports	13.06.1998
EN 1486:1996	Protective clothing for fire-fighters - Test methods and requirements for reflective clothing for specialised fire fighting	03.12.1996
EN 1621-1:1997	Motorcyclists' protective clothing against mechanical impact - Part 1: Requirements and test methods for impact protectors	13.06.1998
EN 1731:1997	Mesh-type eye and face protectors for industrial and non-industrial use against mechanical hazards and/or heat	14.06.1997
EN 1731/A1:1997	Mesh-type eye and face protectors for industrial and non-industrial use against mechanical hazards and/or heat - Amendment 1	13.06.1998
EN 1809:1997	Diving accessories - Buoyancy compensators - Functional and safety requirements, test methods	13.06.1998
EN 1827:1999	Respiratory protective devices - Half masks without inhalation valves and with separable filters to protect against gases or gases and particles or particles only - Requirements, testing, marking	24.02.2001
EN 1835:1999	Respiratory protective devices - Light duty construction compressed air line breathing apparatus incorporating a helmet or a hood - Requirements, testing, marking	08.06.2000
EN 1836:1997	Personal eye protection - Sunglasses and sunglare filters for general use	14.06.1997

Reference	Title of the Harmonised Standards	First publication (OJ)
EN 1836/A1:2001	Personal eye protection - Sunglasses and sunglare filters for general use - Amendment 1	21.12.2001
EN 1868:1997	Personal protective equipment against falls from a height - List of equivalent terms	18.10.1997
EN 1891:1998	Personal protective equipment for the prevention of falls from a height - Low stretch kernmantel ropes	06.11.1998
EN 1938:1998	Personal eye protection - Goggles for motorcycle and moped users	04.06.1999
EN ISO 4869-2 :1995	Acoustics - Hearing protectors - Part 2 : Estimation of effective A-weighted sound pressure levels when hearing protectors are worn (ISO 4869-2:1994)	15.05.1996
EN ISO 6942:2002	Protective clothing - Protection against heat and fire - Method of test: Evaluation of materials and material assemblies when exposed to a source of radiant heat (ISO 6942:2002)	28.08.2003
EN ISO 10819:1996	Mechanical vibration and shock - Hand-arm vibration - Method for the measurement and evaluation of the vibration transmissibility of gloves at the palm of the hand (ISO 10819:1996)	03.12.1996
EN 12083:1998	Respiratory protective devices - Filters with breathing hoses, (Non-mask mounted filters) - Particle filters, gas filters and combined filters - Requirements, testing, marking	04.07.2000
EN 12270:1998	Mountaineering equipment - Chocks - Safety requirements and test methods	16.03.2000
EN 12275:1998	Mountaineering equipment - Connectors - Safety requirements and test methods	16.03.2000
EN 12276:1998	Mountaineering equipment - Frictional anchors - Safety requirements and test methods	24.02.2001
EN 12277:1998	Mountaineering equipment - Harnesses - Safety requirements and test methods	06.11.1998
EN 12278:1998	Mountaineering equipment - Pulleys - Safety requirements and test methods	06.11.1998
EN 12419:1999	Respiratory protective devices - Light duty construction compressed air line breathing apparatus incorporating a full face mask, half mask or quarter mask - Requirements, testing, marking	05.11.1999
EN 12477 :2001	Protective gloves for welders	10.08.2002
EN 12492:2000	Mountaineering equipment - Helmets for mountaineers - Safety requirements and test methods	21.12.2001
EN 12492/A1:2002	Mountaineering equipment - Helmets for mountaineers - Safety requirements and test methods - Amendment 1	28.08.2003
EN 12568:1998	Foot and leg protectors - Requirements and test methods for toecaps and metal penetration resistant inserts	06.11.1998
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- (1) ESO: European Standardisation Organisation (CEN, CENELEC, ETSI)
- (2) Date from which the use of this standard guarantees a presumption of conformity to the essential requirements it covers.