

GOVERNMENT ORDER
No. 426

of 23rd October 2000,

**that lays down the technical requirements for radio equipment
and telecommunications terminal equipment**

The Government orders, under § 22 of Act No.22/1997 Coll., on technical requirements for products and on amending and complementing certain laws, as amended by Act No71/2000 Coll. (further only "Act") to implement § 11 para 1, § 12 para 1 and 4 and § 13 para. 2 and 4 of the Act:

§ 1

(1) In this Order the following is understood

- a) the telecommunications terminal equipment means a product enabling communication or a relevant component thereof which is intended to be connected to interfaces of public telecommunications networks ¹⁾,
- b) the radio equipment means a product, or a relevant component thereof, capable of communication by means of the emission and/or reception of radio waves ²⁾ utilising the spectrum allocated to terrestrial/space radiocommunications ³⁾,
- c) the apparatus is an apparatus which is
 - 1. a part or a separate technical unit of a motor vehicle intended for operation on public roads, with body or without, with at least four wheels and maximum design speed exceeding 25 km p.h., including trailed vehicles, except rail vehicles and agricultural or forestry tractors and self-propelled working machines and mounted working machines, or
 - 2. a part or a separate technical unit of a two-wheel/three-wheel motor vehicle intended for operation on public roads and parts or technical groups of such vehicles except for:
 - 2.1. vehicles with maximum design speed not exceeding 6 km p.h.,
 - 2.2. treadle drive vehicles,
 - 2.3. vehicles intended for physically handicapped persons,
 - 2.4. vehicles intended for road/off-road racing,

¹⁾ § 2 para 4 of Act No 151/2000 Coll., on telecommunications and on amending further Acts.

²⁾ § 2 para 12 of Act No 151/2000 Coll.

³⁾ § 94. g) and § 95 point 1.. b) of Act No 151/2000 Coll.

- 2.5. vehicles that have been operated prior to the effective date of this Order,
 - 2.6. tractors and machines used for agricultural or other purposes,
 - 2.7. vehicles designed originally for being operated off the public roads for leisure, having symmetrically arranged wheels with one front wheel and two rear wheels,
 - 2.8. parts or components of the above vehicles except for those that are intended for two-wheel or three-wheel motor vehicles intended for the operation on public roads.
3. parts or a separate technical unit of motor vehicles having four wheels and the following characteristics:
 - 3.1. mass in empty condition does not exceed 350 kg (in case of electric vehicles the mass of the batteries is not included), the maximum design speed does not exceed 45 km.p.h. and the cylinder volume does not exceed 50 ccm in spark ignition engines with ignition plug or maximum net output does not exceed 4kW in the other types of engines, or
 - 3.2. the mass in empty condition does not exceed 400 kg or 550 kg in vehicles intended for transporting goods (in case of electric vehicles with maximum net output of the engine not exceeding 15 kW the mass of batteries is not included in the overall mass),

(further only "apparatus and equipment").

(2) In this Order the following is further understood

- a) harmful interference means interference which endangers the functioning of a radionavigation service or of other safety services or which otherwise seriously degrades, obstructs or repeatedly interrupts a radiocommunications service operating in accordance with the valid regulations.
- b) the specified products under § 12 para. 1 of the Act are the apparatus and equipment specified in para 1.

§ 2

(1) This Order relates to apparatus and equipment, except for apparatus and equipment set out in Annex 1 to this Order.

(2) If the apparatus and equipment incorporates, as an integral part or as an accessory

- a) a medical device within the meaning of a special legal regulation ⁴⁾,
 - b) an active implantable medical devices within the meaning of a special legal regulation ⁵⁾,
- they are subject to this Government Order.

⁴⁾ Government Order No 180/1998 Coll., stipulating technical requirements relating to devices of medical technology, as amended.

⁵⁾ Government Order No 198/1999 Coll., stipulating technical requirements relating to active implantable medical devices.

(3) The determined products shall meet the following essential requirements

- a) the protection of the health and the safety of the user and any other person, including the objectives with respect to safety requirements contained in a special legal regulation ⁶⁾, but with no voltage limit applying,
- b) the protection requirements with respect to electromagnetic compatibility contained in a special legal regulation ⁷⁾,
- c) a radio equipment shall be so constructed that it effectively uses the spectrum allocated to terrestrial/space radio communication and orbital resources so as to avoid harmful interference.

(4) Selected telecommunication terminals and radio equipment the list of which is published by the Czech Telecommunication Office (further only "Office") in the "Telecommunication bulletin" ⁸⁾, shall be designed so that

- a) it interworks via networks with other equipment and that it can be connected to interfaces of the appropriate type throughout the territory of the Czech Republic,
- b) it does not harm the public telecommunications network or its functioning nor misuse network resources, thereby causing an unacceptable degradation of the service quality;
- c) it incorporates safeguards to ensure that the personal data and privacy of the user and of the subscriber are protected,
- d) it supports certain features ensuring avoidance of fraud,
- e) it supports certain features ensuring access to emergency services,
- f) it supports certain features in order to facilitate its application by users with a disability.

(5) If the apparatus and equipment are subject also to other Government Orders stipulating technical requirements concerning the products, the apparatus and equipment shall meet also the requirements contained in such orders.

(6) If the requirements relating to apparatus and equipment are detailed by harmonised standards under § 4a para 1 of the Act or by foreign technical standards reflecting a harmonised European standard and the characteristics of the apparatus and equipment comply with them, it is understood that such essential requirements under para 3 have been met.

§ 3

~~–(1) Prior to placing the apparatus and equipment on the market, the manufacturer or importer shall ensure the conformity assessment of the apparatus and equipment under § 12 para 4 of the Act with the essential requirements contained in § 2 para 3 according at his choice using one of the following procedures~~

⁶⁾ Government Order No 168/1997 Coll., stipulating technical requirements relating to low voltage electric equipment.

⁷⁾ Government Order No 169/1997 Coll., stipulating technical requirements relating to products concerning their electromagnetic compatibility.

⁸⁾ § 4 para 4 of Act No 151/2000 Coll., on telecommunications and on amending of further acts

- ~~a) if harmonised standards have been used, radio equipment not within the scope of para. a) shall be subject to the procedures described in any one of Annexes 3, 4 or 5,~~
- ~~b) if the harmonised standards have not been used, or have been used partially, radio equipment not within the scope of para. a) shall be subject to the procedures described in any one of Annexes 4 or 5.~~

~~–(2) In addition to procedures laid down in para 1 the compliance of apparatus and equipment with the essential requirements contained in § 2 para 3 can be proven by way of procedures contained in special legal regulations⁶⁾⁷⁾, if they are subject to such special legal regulations.–~~

~~–(3) Records and correspondence relating to the conformity assessment procedures referred to in paragraph 1 shall be in Czech or English.–~~

~~–(4) The manufacturer or importer shall issue a declaration of conformity (§ 9) to each apparatus and equipment and shall affix the Czech conformity mark⁹⁾ on each apparatus and equipment.~~

~~—(5) The manufacturer or importer shall provide information for users on the intended use of the apparatus and equipment together with the declaration of conformity to the essential requirements. Where it concerns radio equipment, such information shall be sufficient to identify on the packaging and the instructions for use of the equipment to potential restrictions or requirements for authorisation of use of the radio equipment and shall alert the user by the marking on the equipment referred to point 5 Annex 7 to any potential restrictions or the authorisation to use radio equipment, in particular whether the equipment is subject to general licence or whether an individual licence is required for its use. Where it concerns telecommunications terminal equipment such information shall be sufficient to identify interfaces of the public telecommunications networks to which the equipment is intended to be connected. For all radio equipment and telecommunications terminal equipment such information shall be prominently displayed.~~

~~(6) In the case of radio equipment using frequencies or frequency bands contrary to the allocation plan of frequencies and frequency bands in the Czech Republic the manufacturer or importer shall notify the authority responsible for the frequency spectrum management¹⁰⁾ of the intention to place such equipment on the market of the Czech Republic. This notification shall be given four weeks in advance of the start of placing of the equipment on the market and shall provide information about the radio characteristics of the equipment, in particular the frequency bands, the channel spacing, type of modulation and RF power and the identification number of the authorised person.–~~

~~–(7) Where the apparatus and equipment is subject to other government orders which concern other aspects and also provide for issuance of declaration of conformity, possibly also the affixing of the CE conformity marking, then the CE marking shall indicate that the apparatus and equipment also fulfils the provisions of those government orders. In this case the documents, notices or instructions required by those government orders and accompanying such products shall refer to such government order.–~~

⁹⁾ Government Order No 179/1997 Coll., laying down the graphical form of the Czech CE mark, its execution and positioning on the product.

¹⁰⁾ § 56 para 1 and § 95 point 5 .a) of Act 151/2000 Coll., on telecommunications and on amending further Acts.

§ 4

(1) Prior to placing the apparatus and equipment on the market, the manufacturer or his authorised representative established within the Community or the person responsible for placing the apparatus and equipment on the market shall ensure the conformity assessment of the apparatus and equipment under § 12 para 4 of the Act with the essential requirements according at his choice using one of the following procedures

- a) telecommunications terminal equipment which does not make use of the spectrum allocated to terrestrial/space radio communication and receiving parts of radio equipment shall be subject to the procedures described in Annexes 2, 4 or 5,
- b) if harmonised standards have been used, radio equipment not within the scope of para. a) shall be subject to the procedures described in any one of Annexes 3, 4 or 5,
- c) if the harmonised standards have not been used, or have been used partially, radio equipment not within the scope of para. a) shall be subject to the procedures described in any one of Annexes 4 or 5.

(2) In addition to procedures laid down in para 1 the compliance of apparatus and equipment with the essential requirements contained in § 2 para 3 can be proven by way of procedures contained in special legal regulations ^{6) 7)}, if they are subject to such special legal regulations.

(3) Records and correspondence relating to the conformity assessment procedures referred to in paragraph 1 shall be in an official language of the Member State where the procedure will be carried out, or in a language accepted by the notified body involved according to § 11 and 11a of the Act.

(4) The manufacturer or his authorised representative established within a member state of the European Union or the person responsible for placing the apparatus and equipment on the market will provide the declaration of conformity to the essential requirements for every apparatus and equipment and affix on it the CE mark according to Annex 7, adding the year in which the conformity was assessed next to the mark. Apparatus and equipment shall be identified by the manufacturer by means of type, batch and/or serial numbers and by the name of the manufacturer or the person responsible for placing the apparatus on the market. Where the procedures identified in Annex 3, 4 or 5 are used, the marking shall be accompanied by the identification number of the notified body according to Annex 6. Radio equipment shall in addition be accompanied by the equipment class identifier according to Annex 7. Any other marking may be affixed to the equipment provided that the visibility and legibility of the EC marking is not thereby reduced. No apparatus or equipment, whether or not it complies with the relevant essential requirements, may bear any other marking which is likely to deceive third parties as to the meaning and form of the EC marking specified in Annex 7.

(5) The manufacturer or his authorised representative appointed in a EU member state or the person responsible for placing the apparatus and equipment on the market provides information for users on the intended use of the apparatus and equipment together with the declaration of conformity to the essential requirements. Where it concerns radio equipment, such information shall be sufficient to identify on the packaging and the instructions for use of the equipment to potential restrictions or requirements for authorisation of use of the radio equipment and shall alert the user by the marking on the equipment referred to point 5 Annex 7 to any potential restrictions or the authorisation to use radio equipment. Where it concerns

telecommunications terminal equipment such information shall be sufficient to identify interfaces of the public telecommunications networks to which the equipment is intended to be connected. For all radio equipment and telecommunications terminal equipment such information shall be prominently displayed.

(6) In the case of radio equipment using frequency bands whose use is not harmonised throughout the European Community, the manufacturer or his authorised representative established within the Community or the person responsible for placing the equipment on the market shall notify the authority responsible in the Czech Republic for spectrum management¹⁰⁾ of the intention to place such equipment on the market of the Czech Republic. This notification shall be given not less than four weeks in advance of the start of placing on the market and shall provide information about the radio characteristics of the equipment, in particular frequency bands, channel spacing, type of modulation and RF-power, and the identification number of the notified body in the member state of the Community referred to in Annex 4 or 5.

(7) Where the apparatus and equipment is subject to other EU directives than the directive on radio equipment and telecommunications terminal equipment and mutual recognition of the ir conformity, which concern other aspects and also provide for issuance of declaration of conformity, possibly also the affixing of the CE conformity marking, then the CE marking shall indicate that the apparatus and equipment also fulfils the provisions of those directives. In this case the documents, notices or instructions required by those directives and accompanying such products shall refer to such directive in accordance with their publication in the Official Journal of the European Communities.

§ 5

(1) Apparatus and equipment that do not meet the requirements laid down by this Order may not be placed on the market.

(2) In case of radio equipment, including types of radio equipment which cause harmful interferences, including interference with existing or planned services on nationally allocated frequency bands, or where such influences can be reasonably considered, the bodies of surveillance in co-operation with the Office will take all suitable measures according to a special legal regulation¹¹⁾ for prohibiting or reducing their being placed on the market or ensuring their withdrawal from the market.

(3) The surveillance bodies will take action, according to special legal regulations¹¹⁾, against a person who has affixed a marking not in conformity with § 3 para 4 or § 4 para 4 or Annex 7. If the person who affixed the marking is not identifiable, appropriate action may be taken against the holder of the apparatus at the time when non-compliance according to the first sentence was discovered.

§ 6

(1) The provisions of the Government Order laying down technical requirements to products concerning their electromagnetic compatibility⁷⁾ will not be used for apparatus and equipment subject to this Order, except for requirements relating to protection under § 3 para 1 and 3, § 4 para 1 and 2, § 5, § 6, § 7 and Appendices of a special legal regulation⁷⁾.

¹¹⁾ Act No 64/1986 Coll., on the Czech trade inspection, as amended.

(2) The provisions of the Government Order laying down technical requirements to electric equipment of low voltage ⁶⁾ will not be used for apparatus and equipment subject to this Order, except for the aims relating to safety requirements under § 3 para 1, § 4, § 5 and Annex 2 of a special legal regulation ⁶⁾.

§ 7

Documents on the used method of conformity assessment under § 13 para 4 of the Act contain

- a) technical documentation specified in the Annexes to this Order,
- b) documents and findings issued by the authorised person during the conformity assessment process.

§ 8

The authorisation under § 11 of the Act for conformity assessment of apparatus and equipment can be granted exclusively to legal persons only meeting the minimum criteria laid down in Annex 6.

§ 9

~~The declaration of conformity for apparatus and equipment shall be prepared in the Czech language and shall contain the following features:-~~

- ~~a) identification data of the manufacturer or importer issuing the declaration of conformity (trade name, name and surname, residence, place of business and identification number of a natural person or a trade name, seat and identification number of a legal person),~~
- ~~b) identification data of the apparatus and equipment (type number, production batch number, serial number, year of production, in case of radio equipment the frequency bands, channel spacing, type of modulation and RF power), name of manufacturer, in case of imported apparatus also identification data of importer,~~
- ~~c) description and purpose of apparatus and equipment (intended usage determined by manufacturer or importer), further data of the apparatus (data for the identification of the public telecommunications network interface to which the equipment can be connected),~~
- ~~d) list of technical regulations under § 3 of the Act and of harmonised standards used for conformity assessment,~~
- ~~e) data concerning the selected procedure for conformity assessment under § 3 para 1 and 2,~~
- ~~f) if an authorised person participates in conformity assessment, then data concerning such person (trade name, seat, identification number of authorised person) and number and date of the findings concerning the apparatus and equipment, reference to the conformity assessment certificate of type of apparatus and equipment issued by the authorised person,~~
- ~~g) certificate of manufacturer or importer confirming compliance of the apparatus and equipment with the essential requirements and, possibly, the requirements of other technical regulations, and that the apparatus and the equipment is, under conditions of current use, or possibly use determined by the manufacturer or importer, safe,~~
- ~~h) date and place of the declaration of conformity issuing, name and position of a responsible person of the manufacturer or importer and his/her signature~~

§ 10

(1) Apparatus and equipment approved before June 30, 2000 according to the Decree of the Ministry of Economy No 26/1996 Coll., on methods, conditions and procedure for the verification and approval of telecommunications terminal equipment, can be placed on the market before June 30, 2002 by the latest.

(2) The duties of the authorised person will be fulfilled by the Office ¹²⁾ until the agreement on the accession of the Czech Republic to the European Union will entry into force.

§ 11

(1) This Government Order entry into force of May the 1st, 2001, except for the provision of § 4, what entry into force of the day the agreement on the accession of the Czech Republic to the European Union entry into force.

(2) § 3 and 9 lose their efficiency as of the day the Czech Republic will have become a member of the European Union.

Prime Minister:

¹²⁾ § 95 point 2.,a) of the Act No 151/2000 Coll., on telecommunications and on amending further Acts.

APPARATUS AND EQUIPMENT NOT COVERED BY THE GOVERNMENT ORDER

1. Radio equipment used by radio amateurs within Article 1, definition 53 of the International Telecommunications Union (ITU) radio regulations unless the equipment is available commercially. Kits of components to be assembled by radio amateurs and commercial equipment modified by and for the use of radio amateurs are not regarded as commercially available equipment.
2. Equipment classified as ship equipment, where
 - 2.1. equipment is understood as objects that must be located on board a ship for use in order to comply with international instruments or are voluntarily placed on board for use, and for which the approval of the flag State administration is required according to international instruments
 - 2.2. radiocommunications equipment is the equipment required by Chapter IV of the International convention on security of life at sea (SOLAS 1974, as amended)
 - 2.3. Such equipment is intended for use on
 - a) a new ship registered in a EU member state irrespective of whether or not the ship is situated within the EU member state territory at the time of construction.
 - b) an existing ship registered in a EU member state
 - where such equipment was not previously carried on board, or
 - where equipment which was previously carried on board the ship is replaced, except where international conventions permit otherwise, whether or not the ship is situated on the territory of a EU member state when the equipment is placed on board
3. Cabling and wiring.
4. Receive only radio equipment intended to be used solely for the reception of sound and TV broadcasting.
5. Products, appliances and components in the field of civil aviation:
 - a) product (civil aircraft, engine, propeller or appliance),
 - b) equipment (instrument, equipment, mechanism, apparatus or accessory used or intended to be used in operating an aircraft in flight, whether installed in, intended to be installed in, or attached to, a civil aircraft, but not forming part of an airframe, engine or propeller),
 - c) component (material, part or sub-assembly not covered by definitions in a) or b) for use on civil aircraft, engines, propellers or appliances).
6. Equipment and systems for air traffic management, especially
 - communication systems,
 - surveillance systems,

- systems providing automated assistance to air traffic control,
- navigation systems.

7. Apparatus or equipment solely used for

- a) tasks of intelligence services¹³⁾,
- b) safety related tasks of the Police of the Czech Republic¹⁴⁾ or
- c) investigation service of the Customs Office¹⁵⁾,
- d) tasks of the Armed Forces of the Czech Republic¹⁶⁾.

¹³⁾ Act No 67/1992 Coll., on Military defence intelligence,
Act No 154/1994 Coll., on Safety information service, as amended by Act No 160/1995 Coll.

¹⁴⁾ Act No 283/1991 Coll., on the Police of the Czech Republic as amended.

¹⁵⁾ § 37c b) of Act No 13/1993 Coll., Customs law as amended by Act No 113/1997 Coll.

¹⁶⁾ Act No 219/1999 Coll., on Armed Forces of the Czech Republic.

CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN § 3 para 1. a) or § 4 para 1 a)

(Internal production control)

1. This conformity assessment procedure relates to the cases where the manufacturer or importer under § 3 or the manufacturer or his authorised representative proceeding under § 4, fulfilling duties determined in point 2, maintains and declares that the respective products meet the requirements of this Order pertaining to them. The manufacturer or importer, proceeding under § 3, will affix to each product the Czech mark of conformity and the manufacturer or his authorised representative, proceeding under § 4, will affix to each equipment a CE mark and issue a written declaration of conformity.
2. The manufacturer must establish the technical documentation described in point 4. The exporter or the importer, proceeding under § 3, or the manufacturer or his authorised representative, proceeding under § 4, shall keep this documentation available for surveillance bodies for inspection purposes, for a period ending at least 10 years after the last product has been manufactured,.
3. If a manufacturer proceeding under § 3 or the manufacturer or his authorised representative proceeding under § 4 do not have their seat in the Czech Republic, the duty of keeping the technical documentation in available condition is conferred on the person placing the products on the market in the Czech Republic.
4. The technical documentation must enable the conformity of the product with the essential requirements to be assessed. It must cover the design, manufacture and operation of the product, in particular
 - a general description of the product,
 - conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
 - descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product,
 - a list of the standards referred to in § 2 para 6, applied in full or in part, and descriptions and explanations of the solutions adopted to meet the requirements of this Government Order where such standards referred to in § 2 para 6 have not been applied or do not exist,
 - results of design calculations made, examinations carried out, etc.,
 - test reports.
5. Manufacturer or importer proceeding under § 3, or manufacturer or his authorised representative proceeding under § 4 must keep a copy of the declaration of conformity with the technical documentation, if it has been issued.

6. The manufacturer must take all necessary measures in order that the manufacturing process ensures compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of this Order that apply to them.

CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN § 3 para 1 b) or in § 4 para 1b)

(Internal production control plus specific apparatus tests)

This procedure is governed by Annex 2 plus the following supplementary requirements:

1. For each type of apparatus and equipment, all essential radio test suites must be carried out by the manufacturer or on his behalf. The identification of the test suites that are considered to be essential is the responsibility of an authorised person (notified body in a EU member country, further only "notified body") chosen by the manufacturer except where the test suites are defined in the harmonised standards. The authorised person (notified body) must take due account of previous decisions made by authorised persons (notified bodies) acting together.
 2. The manufacturer or the importer proceeding under § 3, or the manufacturer or his authorised representative proceeding under § 4 or the person responsible for placing the apparatus on the market must declare that these tests have been carried out and that the apparatus complies with the essential requirements and must affix the authorised person's (notified body's) identification number during the manufacturing process.
 3. Duties under point 1 and 2 relating to notified persons shall be met only after the Czech Republic's accession to the European Union.
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**CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN § 3 para 1 a) to c),
or § 4 para 1 a) to c).**

(Technical construction file)

This procedure is governed by Annex 3 plus the following supplementary requirements:

1. The technical documentation described in point 4 of Annex 2 and the declaration of conformity to specific radio test suites described in Annex 3 must form a technical construction file.
 2. The manufacturer or importer proceeding under § 3, or manufacturer or his authorised representative proceeding under § 4 or the person responsible for placing the apparatus on the market, must present the file to one or more authorised persons (to one or more notified bodies), each of the notified bodies must be informed of others who have received the file.
 3. The authorised person (the notified body) must review the file and if it is considered that it has not been properly demonstrated that the requirements of the Directive have been met, the notified body may issue an opinion to the manufacturer or importer proceeding under § 3, or to the manufacturer or to his authorised representative when proceeding under § 4 or to the person responsible for placing the apparatus on the market and must inform the other authorised persons (notified bodies) who have received the file accordingly. Such an opinion must be given within four weeks of receipt of the file by the notified body. On receipt of this opinion, or after the end of the four-week period, the apparatus may be placed on the market, without prejudice to the provisions of § 3 para 6 and § 5 para 1.
 4. The manufacturer or the importer proceeding under § 3, or the manufacturer or his authorised representative proceeding under § 4 or the person responsible for placing the apparatus on the market must keep the file so as to be available to surveillance bodies for the purpose of checking, for a period ending at least 10 years after the last apparatus has been manufactured.
 5. Duties under point 2 and 3 relating to notified persons shall be met only after the Czech Republic's accession to the European Union.
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**CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN § 3 para 1 a) to c), or §
4 para 1 a) to c)**
(Full quality assurance)

1. Full quality assurance is the procedure whereby the manufacturer who satisfies the obligations of point 2 ensures and declares that the products concerned satisfy the requirements of the Order that apply to them. The manufacturer must affix the marks referred to in § 3 para 4 proceeding under § 3, or shall place a CE mark on the product when proceeding under § 4 and draw up a written declaration of conformity.
2. The manufacturer must operate an approved quality system for design, manufacture and final product inspection and testing as specified in point 3 and must be subject to surveillance as specified in point 4.
3. *Quality system*
 - 3.1. The manufacturer must lodge an application for assessment of his quality system with an authorised person (notified body).

The application must include:

 - a) all relevant information for the products envisaged,
 - b) the quality system documentation.
 - 3.2. The quality system must ensure compliance of the products with the requirements of this Order that apply to them. All the elements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must ensure a common understanding of the quality policies and procedures such as quality programmes, plans, manuals and records. It must contain in particular and adequate description of:
 - a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality,
 - b) the technical specifications, including the harmonised standards and technical regulations as well as relevant test specifications that will be applied and, where the standards referred to in § 2 para. 6 will not be applied in full, the means that will be used to ensure that the essential requirements of the Government Order that apply to the products will be met,
 - c) the design control and design verification techniques, processes and systematic actions that will be used when designing the products pertaining to the product category covered,
 - d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,
 - e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out, as well as the results of the tests carried out before manufacture where appropriate,
 - f) the means by which it is ensured that the test and examination facilities respect the appropriate requirements for the performance of the necessary test,
 - g) the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.,
 - h) the means to monitor the achievement of the required design and product quality and the effective operation of the quality system.
 - 3.3 The authorised person (the notified body) must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It must presume compliance with these requirements in respect of quality systems that implement the relevant harmonised standard.

The authorised person (the notified body) must assess in particular whether the quality control system ensures conformity of the products with the requirements of this Order in the light of the relevant documentation supplied in respect of points 3.1 and 3.2 including, where relevant, test results supplied by the manufacturer.

The auditing team must have at least one member experienced as an assessor in the product technology concerned. The evaluation procedure must include an assessment visit to the manufacturer's premises. The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

- 3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to uphold it so that it remains adequate and efficient.

The manufacturer or his authorised representative in the Czech Republic must keep the authorised person (the notified body) that has approved the quality system informed of any intended updating of the quality system.

The authorised person (the notified body) must evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in point 3.2 or whether a reassessment is required. It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

4. EC surveillance under the responsibility of the authorised person (notified body).

- 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

- 4.2. The manufacturer must allow the authorised person (notified body) access for inspection purposes to the locations of design, manufacture, inspection and testing, and storage and must provide it with all necessary information, in particular:

- a) the quality system documentation,
- b) the quality records as foreseen by the design part of the quality system, such as results of analyses, calculations, tests, etc.,
- c) the quality records as foreseen by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

- 4.3. The authorised person (the notified body) must carry out audits at reasonable intervals to make sure that the manufacturer maintains and applies the quality system and must provide and audit report to the manufacturer.

- 4.4. Additionally, the authorised person (notified body) may pay unexpected visits to the manufacturer. At the time of such visits, the authorised person (notified body) may carry out tests or have them carried out in order to check the proper functioning of the quality system where necessary; it must provide the manufacturer with a visit report and, if a test has been carried out, with a test report.

5. The manufacturer must, for a period ending at least 10 years after the last product has been manufactured, keep at the disposal of the national authorities.:

- a) the documentation referred to in the point 3.1, b,
- b) the updating referred to in the second paragraph of point 3.4,
- c) the decisions and reports from the authorised person (notified body) which are referred to in the final paragraph of point 3.4 and in points 4.3 and 4.4, so as to be available to surveillance bodies.

6. Each authorised person (notified body) must make available to the other authorised persons (notified bodies) the relevant information concerning quality system approvals including references to the product(s) concerned, issued and withdrawn.

7. Duties related to the notified persons shall be met only after the accession of the Czech Republic to the EU.

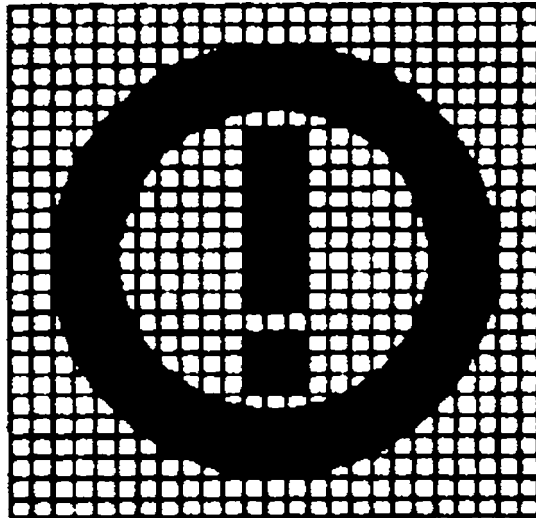
AUTHORISATION TERMS

1. The authorised person, its director and the staff responsible for carrying out the tasks for which the authorised person has been designated must not be a designer, manufacturer, supplier or installer of radio equipment or telecommunications terminal equipment, or a network operator or a service provider, nor the authorised representative of any of such parties. They must be independent and not become directly involved in the design, construction, marketing or maintenance of radio equipment or telecommunication terminal equipment, nor represent the parties engaged in these activities. This does not preclude the possibility of exchanging technical information between the manufacturer and the authorised person (notified body).
 2. The authorised person and its staff must carry out the tasks for which the authorised person (notified body) has been designated with the highest degree of professional integrity and technical competence and must be free from any pressures and inducements, particularly financial, which might influence their judgement or the results of any inspection, especially from persons or groups of persons with an interest in such results.
 3. The authorised person must have at its disposal the necessary staff and facilities to enable it to perform properly the administrative and technical work associated with the tasks for which it has been designated.
 4. The staff responsible for inspections must have
 - sound technical and professional training,
 - satisfactory knowledge of the requirements of the tests or inspections that are carried out and adequate experience of such tests or inspections,
 - the ability to draw up the certificates, records and reports required to authenticate the performance of the inspections.
 5. The impartiality of inspection staff must be guaranteed. Their remuneration must not depend on the number of tests or inspections carried out nor on the results of such inspections.
 6. The authorised person must take out liability insurance unless its liability is assumed by the Member State in accordance with national law, or the Member State itself is directly responsible.
 7. The staff of the authorised person is bound to observe professional secrecy with regard to all information gained in carrying out its tasks under this Order.
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MARKING OF EQUIPMENT REFERRED TO IN § 4

1. The graphical form of the CE marking has been determined by a special legal regulation¹⁷⁾.
If the CE marking is reduced or enlarged, the proportions given on the graduated drawing must be respected.
2. The CE marking must have a height of at least 5 mm except where this is not possible on account of the nature of the apparatus.
3. The CE marking must be affixed to the product or to its data plate. Additionally it must be affixed to the packaging, if any, and to the accompanying documents.
4. The CE marking must be affixed visibly, legibly and indelibly.
5. The equipment class identifier provides information to the user that the apparatus is subject to a restriction regarding its commissioning within the Czech Republic or the European Community.

The identifier has the same height as the initials „CE,, and has the following graphic form:



¹⁷⁾ Government Order No 291/2000 Coll., determining the graphical form of the CE mark.