HANDBOOK FOR IMPLEMENTATION OF RULEBOOK ON THE ELECTROMAGNETIC COMPATIBILITY
Handbook for implementation of Rulebook on the electromagnetic compatibility

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# INSTRUCTIONS FOR IMPLEMENTATION OF RULEBOOK ON THE ELECTROMAGNETIC COMPATIBILITY

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INSTRUCTIONS FOR IMPLEMENTATION
OF RULEBOOK ON THE ELECTROMAGNETIC COMPATIBILITY

1. INTRODUCTION

The instructions have been prepared in order to help all economic operators (manufactures, importers, equipment distributors), and all those involved in design, production and/or trade of equipment which may cause electromagnetic disturbance and/or equipment on which those disturbances can deteriorate its performance. Also, consumers of the Handbook could be other stakeholders who directly or indirectly applies Rulebook on the Electromagnetic Compatibility ("Official Gazette of RS", No. 13/10 – hereinafter referred to as: Rulebook), as conformity assessment designated bodies (hereinafter referred to as: Designated bodies), standardisers, consumer associations, market surveillance authorities and similar.

Intention of the authors of this Handbook is to provide short and concise overview in regards to the:
- application of the Rulebook,
- essential requirements,
- list of Serbian standards accompanying the Rulebook,
- technical documentation,
- the means (module) of conformity assessment,
- the principle of conformity marking with Serbian conformity mark,
- documentation accompanying the product,
- the safeguard clause and
- market surveillance.

Rulebook is aligned with all essential requirements from Directive 2004/108/EC of the European Parliament and the Council of December 15th 2004 relating to electromagnetic compatibility (EMC), which is in line with the commitments of the Republic of Serbia under the Stabilisation and Association Agreement (SAA), and National Programme for Integration of the Republic of Serbia to the European Union (NPI) in regards to the transposition of directives of the European Union (EU) into national legislation, and harmonization of national legislation with the Acquis Communautaire. Obligations from SAA particularly relate to the part referring to the free movement of goods and, in this sense, the necessity of harmonization of technical legislation of the Republic of Serbia with EU technical legislation with the aim to remove technical barriers to trade as one of the key elements for ensuring the free movement of goods and creating a single market.

If the Rulebook is defined from the different perspective, that is, if we say that its primary goal is to harmonize the rules governing the marketing of the equipment to which the Rulebook applies, while at the same time provides an acceptable level of protection of telecommunications and radio systems, energy systems and other electronic equipment from electromagnetic disturbance, then it is justified to conclude that the Rulebook actually represents also a guideline intended for engineers, which must be applied at the beginning of designing equipment with the main objective to provide its placing on the market and/or use. One can say that even a production approach for product, in the scope of this Rulebook is changed.

Rulebook prescribes strengthened exclusive responsibility of the manufacturer that the equipment referred to in the Rulebook, which is placed on the market and/or put into use shall be in conformity with
the essential requirements for electromagnetic compatibility, which is achieved by prescribed internal control of the production. This does not exclude the participation of the designated bodies, as so called third party, in conformity assessment, depending on the needs and choices of the manufacturer, and sometimes they act as additional "control" of the manufacturer.

„manufacturer shall mean a legal person, entrepreneur or natural person that makes a product, or person claiming to be manufacturer by placing on the product its business name, name or title, trademark or other distinctive mark or in any other manner”;

Law on technical requirements for products and conformity assessment ("Official Gazette of RS", No. 36/09)

This Rulebook is accompanied by a list of Serbian standards in the field of electromagnetic compatibility, which is compiled and published by the minister responsible for the adoption of this Rulebook in the "Official Gazette of the Republic of Serbia". These are Serbian standards that transpose harmonized (European) standards in the field of electromagnetic compatibility, adopted by the Institute for Standardization of Serbia, and with whose application the presumption of conformity with essential requirements of this Rulebook is achieved.

The intended purpose of the product is of great importance, because it further determines the application of directives or rulebook.

Rulebook does not imply how the manufacturer should make a product that will be in conformity with the essential requirements for electromagnetic compatibility and place it on the market, but "only" what requirements must be met, and the manner this will be achieved is left to the manufacturer. Among other things, this reflects flexibility of so-called New Approach of the EU.

2. SCOPE OF THE RULEBOOK

The rulebook, in accordance with the transposed directive, provides only the essential requirements for electromagnetic compatibility of the equipment prior to its placing on the market or putting into use.
There are two primary objectives that rulebook must meet: to ensure free and smooth placing of the equipment on the market of the Republic of Serbia; at the same time, to establish an acceptable electromagnetic environment where these appliances can operate freely.

These main objectives are accomplished by ensuring and fulfilling essential requirements for electromagnetic compatibility, namely:

- to ensure that the electromagnetic disturbance produced by the equipment in its environment does not affect the proper functioning of other equipment;
- to ensure the immunity of the equipment, that is, ability to perform without deterioration, in accordance with the intended purpose, in the presence of electromagnetic disturbance.

The fulfilment of essential requirements does not guarantee, nor is it possible to guarantee absolute protection of the equipment (e.g. zero-emission level or complete immunity).

2.1. Products covered by the Rulebook

By entering into force and with the beginning of full application (20th March 2010) the Rulebook has generated the greatest number of questions regarding the scope, that is, to which products does the Rulebook apply to?

![Flowchart 1 – Scope](image)

This Rulebook applies to all equipment liable to cause electromagnetic disturbance, and/or the performance of which is liable to be affected by such disturbance. Therefore, it applies to electrical and electronic appliances, systems and fixed installations.

The application of this Rulebook shall not affect the application of specific regulations regulating the safety of equipment.
The Rulebook defines equipment as **apparatus or fixed installation**.

Because of the different requirements, stipulated in the Rulebook it is very important to define equipment in a proper way, in line with Flowchart 2.

**What is „apparatus“?**

Flowchart 2 – Classification of apparatus

Rulebook defines "apparatus" as any finished appliance or combination thereof with the function intended for the end user and intended to be placed on the market as a single commercial unit and liable to generate electromagnetic disturbance or the performance of which is liable to be affected by such disturbances, as well as:

- components or sub-assemblies intended for incorporation into an apparatus by the end user, which are liable to generate electromagnetic disturbances, or the performance of which is liable to be affected by such disturbances;
- mobile installations defined as a combination of apparatus and, where applicable, other apparatus intended to be moved and operated in different locations.

The most important precondition to consider any appliance or combination of appliances as an apparatus in terms of the Rulebook is:

- that the device is intended for the end user,
- that the device is able to cause electromagnetic disturbance, or may be affected by such disturbance in its intended purpose.

If both conditions are not fulfilled due to the very nature of the apparatus, then we can say it is a **benign apparatus**, and that on such apparatus the Rulebook is not applicable.
Finished appliances

Finished appliance is any appliance that is delivered as a single functional unit (it is packed in its “case”) on the market and it is intended for end user.

When that appliance is intended exclusively for an industrial assembly operation or incorporation into other apparatus, such an appliance shall not be considered as an apparatus in terms of this Rulebook.

Combination of finished appliances (systems)

Combination of finished appliances (systems) is combination of more finished appliances that are as a single functional unit placed on the market. Such a system, in order to be considered apparatus in terms of the Rulebook, must be combined, and/or designed and/or put together by the same person (“manufacturer”).

Components or sub-assemblies Rulebook applies to

Components or sub-assemblies on the market intended for incorporation into an apparatus by the end user and which are available to the end user are considered as apparatus in respect to the application of this Rulebook.

Typical examples for named components or sub-assemblies are:
- “Plug-in” cards for computer;
- Programmable logic controllers;
- Electric motors (except for induction motors);
- Power supply units, where they take the form of autonomous equipment or which are sold separately, for installation by the end user;
- Computer disk drives;
- Electronic temperature controls, etc.

In this case attention should be paid to the instruction manual. It should be assumed that adjustments or incorporation can be made by the end users who are not aware of the consequences of electromagnetic compatibility.
Mobile installations

Mobile installations (e.g. a portable broadcast studio) which are defined as a combination of apparatus (and where applicable other devices) intended to be moved and operated in a different locations are considered to be apparatus in terms of this Rulebook.

What is „fixed installation”?

Rulebook prescribes that a fixed installation is a particular combination of several types of apparatus and other devices, which are assembled, installed and intended to be used permanently at a predetermined location.

The definition covers all installations from the smallest residential electrical installation through to national electrical and telephone networks, including all commercial and industrial installations.

The EMC Directive, that is, the Rulebook excludes benign installations. However, “a- priori” application of this exclusion criterion seems problematic, so it is used on a case–by-case basis.

The term “fixed installation” also applies to large machines if they meet the definition of fixed installations, for example, production lines. Large machines, in the common sense of this term, are normally apparatus and they have to be treated as such.

Examples of fixed installations: Industrial plants; power plants; power supply networks; telecommunication networks; cable TV networks; computer networks; airport luggage handling installations; airport runway lighting installations (systems); automatic warehouses; skating hall ice rink machinery installations; storm surge barrier installations (systems) (with the control room, etc); wind turbine stations; car assembly plants; water pumping stations; water treatment plants; railway infrastructures; air conditioning installations.

Flowchart 4 – Installations

Apparatus placed on the market, and incorporated into fixed installations, certain provisions of the Rulebook relating to apparatus, are applicable to, that is, such apparatus have to comply with the requirements set in the Rulebook.

However, for apparatus intended for incorporation into a fixed installation, and otherwise are not intended to be placed on the market, that is, they are not commercially available, the Rulebook does not apply.
2.2. Products not covered by the Rulebook

Generally speaking, equipment which does not contain electrical and/or electronic parts will not create electromagnetic disturbances and its normal operation is not affected by such disturbances. Therefore, equipment without electrical and/or electronic parts is not in the scope of the Rulebook, that is, the provisions of the Rulebook do not apply to such equipment.

Rulebook explicitly does not apply to:
- radio equipment and telecommunications terminal equipment which is governed by a different regulation;
  (That different regulation transposed R&TTE directive (1999/5/EC) into national legislation of the Republic of Serbia. This European Directive covers most radio equipment and telecommunication terminal equipment and includes requirements for electromagnetic compatibility. This means “de-facto” that the requirements for electromagnetic compatibility from EMC directive, that is, from the Rulebook are obligatory for R&TTE equipment).
- aeronautical products, parts and appliances on which regulations from the field of civil aviation are applied to;
- radio equipment used by radio amateurs, unless that equipment is placed on the market independently.

Equipment covered by specific regulations

Such equipment is:
- Motor Vehicles - Electromagnetic compatibility (motor vehicles), electronic sub-assemblies and post-market electronic equipment (equipment which is independently placed on the market) related to immunity, and components-parts that are sold as a post-market equipment (equipment that is individually placed on the market) and is intended for installation into motor vehicles also from the aspect of immunity;

Equipment satisfying the requirements for exemption of type approval under the motor vehicle EMC directive must meet the essential requirements of this Rulebook.
- Active implantable Medical Devices: Directive 90/385/EEC
- Medical Devices: Directive 93/42/EEC;
- In vitro Diagnostic Medical Devices: Directive 98/79/EC;
- Marine equipment: if covered by Directive 96/98/EC;
- Agricultural and forestry tractors covered by Directive 75/322/EEC;
- Two or three-wheel motor vehicles within scope of Directive 97/24/EC;

Benign equipment

Equipment is considered benign in terms of this Rulebook, if:
- its physical characteristics are such that it is incapable of creating or contributing to electromagnetic emissions,
- it can operate without deterioration in the presence of the electromagnetic disturbance.

Components /sub-assemblies

Components and sub-assemblies, as well as those intended for incorporation into apparatus and/or another sub-assembly by persons other than the end user are not considered as apparatus in regards to this Rulebook.
Typical examples are:
- resistors, capacitors, inductors, filters;
- diodes, transistors, thyristors, triacs, etc;
- integrated circuits;
- simple electromagnetic relays;
- LEDs - light emitting diode;
- simple thermostats;
- cathode ray tubes.

3. ESSENTIAL REQUIREMENTS

Essential requirements for electromagnetic compatibility are prescribed in Annex 1. It can be said that this methodology directly introduces specific procedures which become an integral part of the design process and manufacturing of products.

Rulebook defines the essential requirements, such as: general requirements relating to all equipment (appliances and fixed installations) and special requirements relating to fixed installations.

Essential requirements aim to protect public and general interests.

General requirements for equipment ensure:

1) the electromagnetic disturbances generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended;

2) that equipment has a level of immunity to the electromagnetic disturbances to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use.

The specific essential requirements for fixed installations prescribe that fixed installations need to be installed taking into account of good engineering practice in the field of electromagnetic compatibility and taking into account the information on the intended use of its components, in order to meet protection requirements referring to general requirements for equipment. Good engineering practice is documented and the documentation is kept by the person responsible who is obliged to make it available and at disposal to the relevant authorities for inspection purposes for as long as the fixed installation is in operation.

4. LIST OF SERBIAN STANDARDS ACCOMPANYING THE RULEBOOK AND PRESUMPTION OF CONFORMITY

Harmonized standards in the field of electromagnetic compatibility are transposed and adopted as Serbian standards by the Institute for Standardization of Serbia. List of adopted Serbian standards transposing harmonized standards is compiled, updated and published in accordance with the Law on technical requirements for products and conformity assessment and the regulation adopted on the basis of that Law.

Presumption of conformity

Conformity mark and Declaration of conformity as presumption of conformity

This kind of presumption of conformity of equipment with the requirements of the Rulebook is in fact derived indirectly. Conformity mark, placed on the equipment, and the Declaration of conformity are the external appearances that indicate the existence of the presumption of conformity of electrical equipment with the requirements of the Rulebook.

Application of standards from the List of Serbian standards in the field of electromagnetic compatibility as a presumption of conformity

It is considered that the equipment meets the essential requirements referred to in Annex 1, if it is made in accordance with Serbian standards in the field of electromagnetic compatibility which transposed appropriate harmonized standards. In other words it could be said that the equipment complies with the
essential requirements until it is proven otherwise. More, such equipment is placed on the market and/or put into use freely without any restrictions.

The manufacturer can design and manufacture the equipment, without applying any of the standards from the list of standards or with applying only parts of a standard. In this case, the manufacturer, through technical documentation, must prove that such technical solution fully complies with all essential requirements prescribed by the Rulebook.

Therefore, it can be concluded that the use of Serbian standards from the list of standards is the simplest and fastest tool in the procedure of "confirming" that the product is in compliance with essential requirements.

5. TECHNICAL DOCUMENTATION

In regards to the Rulebook (and all other regulations transposing New Approach and Global Approach Directives) technical documentation is documentation providing evidence of conformity of the product with requirements of all relevant technical regulations relating to the given product.

Drawing up technical documentation includes knowledge, procedures and skills that engineers acquire on undergraduate and master studies. This activity does not require any special licence.

Essential characteristics:

- Technical documentation must confirm that equipment complies with requirements from the Rulebook;
- Technical documentation includes design, manufacture and operation of the equipment to the extent it is necessary for conformity assessment;
- Technical documentation must be written in Serbian language, or in any of the official languages of the EU, with relevant translation into Serbian;

Technical documentation is defined in Annex 4 of the Rulebook.

The manufacturer is entirely responsible and obliged to take all actions and measures to ensure that the manufactured equipment is in conformity with all relevant requirements prescribed in the Rulebook. Conformity must be ensured before the equipment is placed on the market. For this purpose, the manufacturer has the exclusive right and obligation to prepare and draw up technical documentation. Manufacturer can never transfer these obligations to another person (his agent, importer, distributor, etc.).

Technical documentation includes design, manufacture and operation of the equipment to the extent it is necessary for conformity assessment, and particularly:

- general description of the equipment;
- the list of Serbian standards applied from the list of standards set out in Article 7 of this Rulebook;
- when the manufacturer has not applied Serbian standards from the list of standards, or has partially applied them or if such standards do not exist, a description and explanation of the procedures applied in order to meet the essential requirements prescribed in Annex 1 of the Rulebook, including a description of the performed conformity assessment with the electromagnetic compatibility requirements referred to in point 1 of Annex 2, as well as the results of design calculations made, examinations carried out, test reports, etc.;
- a statement from the Designated Body, when the conformity assessment procedure referred to in Annex 3 has been performed.

The technical documentation must be available to relevant authority at least ten years after the date of the last manufactured specimen of the equipment.

The technical documentation does not have to:
- to be kept on the territory of the Republic of Serbia,
- in one locality,
- to be permanently available in material form.

*Person specified in Declaration of Conformity, must ensure that technical documentation is available, that is, to make it at disposal to competent authorities at their request.*

If manufacturer or his representatives is not registered in the Republic of Serbia, all obligations are taken over by importer of equipment in subject.

## 6. CONFORMITY ASSESSMENT

Rulebook in Annex 4, defines procedures of conformity assessment of equipment-apparatus, which must be carried out **before placing equipment on the market or putting into use**. They can be performed by manufacturer or designated body for conformity assessment.

### Flowchart 5 – Conformity assessment procedure for apparatus

#### 6.1. Conformity assessment carried out by manufacturer

The procedure applied, is the procedure of **conformity assessment of equipment by internal production control** referred to in Annex 2 of the Rulebook. This procedure does not involve the participation of the designated body.

Internal production control is the basic conformity assessment procedure, prescribed by the Rulebook. This control, implemented by the manufacturer, consists of three essential elements:
- Technical documentation,
- Declaration of Conformity;
- Marking of conformity and conformity mark.

![Internal production control](Picture 6. Internal production control)

6.2. Conformity assessment carried out by Designated body

Rulebook, in Annex 4 prescribes that conformity assessment body may conduct or participate in the conformity assessment of equipment, only if it meets the requirements for designation laid down in Annex 6 of the Rulebook, and if it is designated by the competent minister in accordance with the Law on technical requirements for products and conformity assessment and Regulation on the manner of designation and authorization of conformity assessment bodies ("Official Gazette of RS", No. 98/09).

Declaration confirming conformity of equipment with requirements from the Rulebook, as a type of document of conformity

Activities of conformity assessment that, in accordance with the Rulebook, are performed by the designated body refer to review of technical documentation and assessment, based on the conducted examination whether the technical documentation confirms fulfilment of the requirements from the Rulebook.

If compliance is confirmed, the designated body makes Declaration of conformity confirming compliance of equipment in subject with the requirements of the Rulebook.

Conformity assessment performed in an abovementioned manner, that is, in which the designated body takes part is not mandatory in terms of the Rulebook, but voluntary and depends on the will and needs of the manufacturers. Namely, by choice and upon request of equipment manufacturer or his agent, prior to placing the equipment on the market and/or putting into use, the designated body carries out conformity assessment of equipment with the requirements from this Rulebook. Aspects of essential requirements that need to be assessed are stated in the request. Declaration of Conformity issued by, or drawn up by notified body is limited to those aspects of the essential requirements that designated body has assessed. This declaration, the manufacturer or his agent encloses with technical documentation of equipment in subject and it does not represent a document that accompanies the product on the market.

Confirmation of conformity, as a type of document of conformity

Confirmation of Conformity (an extract from the register of issued certificates) shall be applied in the legal system of the Republic of Serbia until entry into force of ratified International Agreement on Conformity Assessment and Acceptance of Industrial Products with the European Union - ACAA (Agreement on Conformity Assessment and Acceptance of Industrial Products) in part relating to the machinery covered by the Rulebook, and not later than the accession of Serbia to the European Union.

Who issues Confirmation of conformity?

Confirmation of conformity can be issued at request of different economic operators. Request can be submitted by foreign or domestic manufacturer, representative, branch office or representative of foreign manufacturer or importer.
Designated body on the basis of that request, submitted before placing equipment on the market, and enclosed documentation, which is:
- declaration of conformity,
- appropriate technical documentation (usually but not necessarily, the test report, test summary report), reviews the technical documentation and if the conformity of the equipment is confirmed, issues the Confirmation of conformity.

Confirmation of conformity is a document accompanying the product during import and later during placing on the market of the Republic of Serbia, which serves as a proof of conformity and which supplier of the product is obliged to present to the customs official and/or to the relevant authority at request. The Designated body keeps a record of issued confirmations and upon request of manufacturer or his representative and/or importer issues the Excerpt from records. The Designated body publishes the records on issued confirmations on its official webpage.

The obligation to obtain confirmation of conformity is valid for both importers and domestic manufacturers of equipment. As an exception, this obligation does not refer to the manufacturers of the equipment made in the Republic of Serbia and for which conformity assessment has been carried out by the Designated body in accordance with Annex 3 of the Rulebook, that is, appropriate testing (as accredited body) and provided test report which is the integral part of technical documentation of the manufactured equipment in question.

On the basis of the confirmation of conformity or excerpt from the record issued by the designated body, the manufacturer or his authorised representative affixes the Serbian conformity mark on the equipment.
Confirmation of conformity contains, in particular:

- information on business name, and/or name of the manufacturer,
- title of the Rulebook and number of the Official Gazette of the Republic of Serbia,
- type and kind of equipment having conformity confirmed.

Confirmation of conformity can consist of other information, such as information on the applicant requesting issuance of this confirmation, etc.

If a particular equipment is subject of other technical regulations, that prescribe mandatory compliance of that apparatus, prior to its placing on the market, and with the requirements from these regulations, it is necessary that confirmation of conformity includes conformity assessment of apparatus with all technical regulations relating to that apparatus, and if it is not a case, it is recommended that confirmation of conformity, besides requested conformity assessment with requirements from the Rulebook, contains a note other technical regulations the conformity assessment of apparatus in subject will be carried out.

Issued confirmation of conformity is valid for the same type and/or type of product from the same manufacturer for three years from the date of issuance; and issued excerpt from the records has the same period of validity as issued confirmation of conformity in question.

7. MARKING OF CONFORMITY AND ACCOMPANYING DOCUMENTATION

7.1. Marking

Marking and conformity mark of equipment are prescribed in Article 11 and Annex 5 of the Rulebook.

The equipment that is in compliance with requirements from the Rulebook is marked by conformity mark.

![Picture 8. Serbian mark of conformity]

The manufacturer, or his authorised representative, or importer (if the manufacturer or his representative is not registered in the Republic of Serbia) shall affix the conformity mark, so as to be visible, legible and indelible, in accordance with the regulation governing the manner of affixing and use of conformity marks.

Serbian mark is the only label certifying that the product being placed on the market and/or put into use in the Republic of Serbia, is in compliance with the requirements of Serbian technical regulation, if such regulation provides its affixing.
Together with Serbian mark, a unique number of designated body is affixed, if that body performed and/or participated in conformity assessment, as well as last two digits of the year of issuance of declaration of conformity of drawing up declaration of conformity. Affixing of conformity mark is performed:

• by pressing, stamping,
• on the place easily accessible for inspection,
• by indentation on the plate,

*for importers who are not expected to open products*

• by affixing on the product container (or label, slings)
• by affixing on the documentation.

The equipment may be affixed with other signs, symbols, inscriptions or other markings, provided that this does not reduce the visibility, legibility and/or interpretation of a conformity mark.

7.2. Declaration of conformity

The manner in which the conformity mark has been affixed is the first indication for market surveillance authorities that the product complies with the relevant essential requirements of the appropriate applicable regulations and suggests that it is followed by the declaration of conformity.

The declaration of conformity is a document issued or drawn up by the manufacturer or his representative. This document represents a kind of legal statement by which the manufacturer or his representative confirms:

✓ that all relevant requirements of the regulation(s) have been fulfilled;
✓ that he holds technical documentation,
✓ if necessary, holds other documents of conformity, by which undoubtedly confirms the fulfilment of the requirements of technical regulations,
✓ that he is held responsible for conformity of the product with the prescribed requirements, and safety of the products.

The declaration of conformity shall include, in particular:

- business name, or title or the name and address of the manufacturer's seat and, where appropriate, business name or title or the name and address of the seat of his representative;
- description of the equipment with data that allow more detailed identification of the apparatus;
- an explicit statement that the equipment is in compliance with the Rulebook, and the number of the Official Gazette in which the rulebook was published;
- list of Serbian standards from the list of standards referred to in Article 7 of the Rulebook that were applied in manufacture of the equipment;
- references to technical documentation, and the applied technical specifications or other standards, if standards from the list of standards referred to in Article 7 of the Rulebook were not applied;
- information on the declaration of conformity issued by a designated body, if it carried out or participated in the conformity assessment of the equipment in accordance with Article 9 of the Rulebook, as well as information on the designated body that drafted and/or issued the declaration and his unique number from the register of designated conformity assessment bodies;
- last two digits of the year in which the conformity mark was affixed;
- place and date of issuance of the Declaration of Conformity;
- identification and signature of authorized person responsible for issuing the declaration of conformity in name of the manufacturer or his representative.
Supplier, along with the equipment he delivers on the Serbian market, provides a copy of the Declaration of Conformity and its translation into Serbian language if that apparatus was not manufactured in the Republic of Serbia, as well as instruction for use in Serbian language.

Declaration must be provided separately, as a single document and when necessary it can be written on instructions but always with the prescribed content.

7.3. Confirmation of conformity

Confirmation of Conformity is a special type of document of conformity that was introduced in the Serbian technical legislation by "the new technical regulations." The confirmation of conformity is a document certifying the compliance of the product in subject with the requirements of the relevant regulations. It can be issued at the request of various economic operators. The request may be submitted by foreign or domestic manufacturer, agent, representative or branch office or representative of a foreign manufacturer or importer. More on Confirmation of Conformity has been said in Section 6.2. of this Handbook.

7.4. Instructions

The supplier who is placing the equipment on the market of the Republic of Serbia, together with the equipment, encloses instructions in the Serbian language. There is a general agreement that all instructions regarding health and safety requirements must be submitted in writing, because it should not be assumed that the user has means to read the given instructions in electronic form or available on the Internet site.

8. SAFEGUARD CLAUSE

Conformity mark and the Declaration of Conformity for equipment are external indicators that confirm the existence of a presumption of conformity of equipment with the requirements from the Rulebook.

Therefore, the delivery or use of equipment, that is placed on the market of the Republic of Serbia, which meets the requirements of this Rulebook, on which the conformity mark has been affixed, which is accompanied by a declaration of conformity and used in accordance with the intended purpose or under conditions that can be reasonably predicted, it cannot be limited nor its free movement can be affected by other requirements and conditions which are not prescribed by the Rulebook.

Nevertheless, this presumption of conformity can disproved, so that the free movement of such equipment may still be restricted or prohibited only if there is a reasonable doubt that the equipment is unsafe or non-compliance with the essential requirements from Annex 1 of the Rulebook, but that restriction, withdrawal, revocation, or some other kind of prohibition on trade can be executed by a competent market surveillance authorities only according to the procedure and in the manner prescribed by the law governing technical requirements for products and conformity assessment, or by other appropriate law (Article 15 of the Rulebook - safeguard clause).

9. MARKET SURVEILLANCE

Market surveillance over the implementation of the Rulebook should ensure that the Rulebook is applied in practice and that the equipment placed on the market and/or put into use in the Republic of Serbia is safe.

Market surveillance is carried out during or after placing those products on the Serbian market, and/or into their intended use. Market surveillance is different from the conformity assessment because their aim is to ensure conformity of products before they are placed on the market and/or put into use.
Market surveillance can be done at any stage after the completion of the equipment design, as soon as the product is made available for distribution or use in the Republic of Serbia. Equipment can be inspected at the premises of manufacturers, importers, distributors or companies that rent, as well as in transit.

**What does relevant market surveillance authority checks?**

- Conformity mark and declaration of conformity
- Instructions
- Where applicable, documents on conformity to which Declaration of Conformity refers to
- Technical documentation - if the relevant market surveillance authority has reasonable doubt in conformity with the essential health and safety requirements, it may require the submission of technical documentation. Such a request may be submitted at any stage of market surveillance procedure.

*Actions and measures undertaken by the relevant market surveillance authority in the case of non-compliance of all the products with the requirements from every technical regulation, including non-compliance of equipment with the requirements from the Rulebook, are prescribed by the Law on Technical Requirements for Products and Conformity Assessment, and in the absence of some surveillance measures in that Law, other surveillance measures from the Law on General Product Safety are applied.*

10. **CONCLUSION**

Contrary to the Old Approach, the philosophy of the New Approach implies that the European directives define only essential requirements for product safety, and that the detailed technical content, i.e. elaboration of the essential requirements is contained in the so-called harmonized European standards. When requirements of the harmonized standards are met, it is considered that the manufacturer fulfils the essential requirements contained in the New Approach directives (presumption of conformity). Having in mind that fulfilment of requirements from standards is not the only way to ensure conformity with essential requirements; manufacturer can meet essential requirements in another manner. This way the voluntary application of standards is preserved.

Another element of the New Approach represents a way to verify compliance with the essential requirements. Conformity assessment is based on the so-called Global Approach, i.e. modules for conformity assessment. Unlike the Old Approach, compliance with the requirements of the directive is confirmed by the manufacturer – with a declaration of conformity or document of conformity which were issued by designated conformity assessment body, and the government is completely left out from the process of conformity assessment with the prescribed requirements.

Since the Rulebook transposed one of the New Approach directives - EMC 2004/108/EC, the spirit of the New and Global approach is also transferred into technical legislation of the Republic of Serbia. In addition to these basic principles, the Rulebook temporarily introduced, as an additional mechanism for consumer protection, verification of conformity of products performed by the designated bodies.

In accordance with Directive 2004/108/EC, as the so-called New Approach directive in the field of technical legislation of the EU, as well as the law governing the technical requirements for products and conformity assessment, this Rulebook prescribes essential new solutions in the field of electromagnetic compatibility requirements for equipment that can cause electromagnetic disturbance and/or that such disturbances do not affect its normal operation; the new solutions in regards to operators that carry out or participate in the conformity assessment and the types of documents of conformity, as well as in regards to the voluntary application of Serbian standards that transpose harmonized (European) standards in this field (presumption of conformity). This concept differs from concept from earlier rulebooks and ordinances in the field of electromagnetic compatibility, which often contained out of date, inconsistent and too detailed technical and technological solutions and rules, which have, in recent years, started to show unnecessary restrictions and burdens for the manufacturers.
I INTRODUCTION

Scope

Article 1

This Rulebook stipulates the essential requirements that shall be met with regard to the electromagnetic compatibility prior to placing of equipment on the market and/or putting it into service; presumption of conformity; procedures for assessing the conformity of apparatus; conformity mark and conformity marking; the content of Declaration of Conformity and technical documentation; safeguard clause and criteria that shall be met by a conformity assessment body to be notified for conformity assessment.

Application

Article 2

This Rulebook applies on equipment liable to cause electromagnetic disturbance, and/or the performance of which is liable to be affected by such disturbance.

The application of this Rulebook shall not affect the application of specific regulations regulating the safety of equipment.

Equipment and products to which this Rulebook does not apply

Article 3

The provisions of this Rulebook does not apply to following equipment and products:
1) Radio and telecommunications terminal equipment regulated by specific regulation;
2) Aeronautical products, parts and appliances regulated by specific regulations in the field of civil aviation;
3) Radio equipment used by radio amateurs which is not placed on the market as a single unit;
4) Equipment, the inherent nature of the physical characteristics of which is such that:
   (1) it is incapable of generating or contributing to electromagnetic emissions which exceed a level allowing radio and telecommunication equipment and other equipment to operate as intended;
   (2) it will operate in compliance with its intended use in the presence of electromagnetic disturbances without unacceptable degradation of its characteristics.

Kits of components to be assembled by radio amateurs and commercial equipment modified by and for the use of radio amateurs shall not be regarded as radio equipment as per Paragraph 1 (3) of this Article.

This Rulebook shall not apply to equipment for which essential requirements for electromagnetic compatibility under Annex 1 – Essential requirements for electromagnetic compatibility, printed with this Rulebook as its integral part, is more specifically regulated by other regulations.
Definitions

Article 4

For the purpose of this Rulebook, the following definitions apply:

1) “equipment” means any apparatus or fixed installation;

2) “apparatus” means any finished appliance or combination thereof with the function intended for the end user and intended to be placed on the market as a single commercial unit and liable to generate electromagnetic disturbances or the performance of which is liable to be affected by such disturbances, as well as:

   (1) “components” or “sub-assemblies” intended for incorporation into an apparatus by the end user, which are liable to generate electromagnetic disturbances, or the performance of which is liable to be affected by such disturbances;

   (2) “mobile installations” defined as a combination of apparatus referred to in Item 2 of this Article, and, where applicable, other apparatus intended to be moved and operated in different locations.

3) “fixed installation” means a particular combination of several types of apparatus and/or other devices which are assembled, installed and intended to be used permanently at a predefined location;

4) “electromagnetic compatibility” means the ability of equipment to function satisfactory in its electromagnetic environments without introducing intolerable electromagnetic disturbances to other equipment in that environment;

5) “electromagnetic disturbance” means any electromagnetic phenomenon which may degrade the performance of equipment, such as electromagnetic noise, an unwanted signal or a change in the propagation medium itself;

6) “immunity” means the ability of equipment to perform as intended without degradation in the presence of an electromagnetic disturbance;

7) “safety purpose” means the purpose of safeguarding human life or property;

8) “electromagnetic environment” means all electromagnetic phenomena observable in a given location;

9) “placing on the market” means making available for the first time in the Republic of Serbia a product for the purpose of distribution or use, in return for payment or free of charge;

10) “putting into service” means the first use of equipment for its intended purpose in the territory of the Republic of Serbia;

11) „manufacturer” means any natural or legal person or entrepreneur who designs and/or manufactures equipment with a view to its being placed on the market, under his own business name or trademark or other recognisable label or for his own use. In the absence of a manufacturer as defined above, any natural or legal person or entrepreneur who places equipment on the market or puts into service shall be considered a manufacturer;

12) „authorised representative” means any legal entity or entrepreneur registered in the Republic of Serbia or natural person who is resident in the Republic of Serbia who has been authorised by the manufacturer to perform on his behalf all or part of the obligations under this Rulebook;

13) “harmonised standard” means a standard adopted by European Standards Bodies, such as: the European Committee for Standardisation (CEN); the European Committee for Electrotechnical Standardization (CENELEC) or the European Telecommunications Standards Institute (ETSI) on the basis of an order of European Commission which is published in the Official Journal of the European Union;

14) “good engineering practice” means confirmed (verified) solution from the practice with regard to design, manufacturing or assembly of equipment whose application ensures that the equipment meets safety requirements if it used for its intended purpose.

Terms used in this Rulebook which are not defined under Paragraph 1 of this Article, have meanings stipulated by laws regulating technical requirements for products, general safety of products and standardisation.
II PLACING ON THE MARKET AND/OR PUTTING INTO SERVICE

Placing on the market and/or putting into service

Article 5

The equipment to which this Rulebook applies shall be placed on the market and/or put into service in the Republic of Serbia only if it is in conformity with the essential requirements for electromagnetic compatibility specified in Annex 1 provided that it is properly installed, maintained and used for its intended purpose.

Free movement

Article 6

Equipment which complies with requirements under this Rulebook shall be placed on the market and/or put into service freely, without limitations.

The requirements stipulated by this Rulebook shall not affect the application of the following special measures concerning the putting into service or use of equipment:

1) measures to overcome an existing or predicted electromagnetic compatibility issue at a specific site;
2) measures taken for safety reasons to protect public telecommunications networks or receiving or transmitting stations when used for safety purposes in well-defined spectrum situations.

The equipment which does not comply to the requirements of this Rulebook may be displayed at trade fairs, exhibitions or similar events, provided that a visible sign clearly indicates that such equipment will not be placed on the market and/or put into service until it has been brought into conformity.

Public display and presentation of the equipment referred to in Paragraph 3 of this Article shall be performed provided that adequate measures are taken to avoid electromagnetic disturbances.

III PRESUMPTION OF CONFORMITY

Serbian standards transposing harmonised standards

Article 7

Equipment shall be considered to comply with the essential requirements set out in Annex 1, if it is designed and manufactured in accordance with Serbian standards relating to electromagnetic compatibility which transposed relevant harmonised standards, the list of which (hereinafter referred to as: List of standards) is made and published in accordance with the law governing technical requirements for products and conformity assessment and the regulation adopted on the basis of that law.

This presumption of conformity as per Paragraph 1 of this Article is limited to the scope of the harmonised standard(s) applied from the list of standards and the relevant essential requirements covered by such standard(s).

IV PROCEDURES FOR ASSESSING THE CONFORMITY OF APPARATUS

Conformity assessment procedure applied by manufacture

Article 8

Assessment of conformity of apparatus with the essential requirements under Annex 1 shall be demonstrated by the manufacturer by means of the internal production control as set out in Annex 2 –
Conformity assessment carried out by the manufacturer (Internal production control), which is printed with this Rulebook as its integral part.

**Conformity assessment procedure applied by the Notified Body for conformity assessment**

**Article 9**

Conformity assessment body may conduct the assessment of conformity if it fulfils criteria for conformity assessment specified in Annex 6 – Criteria to be taken into account for the notification of bodies for assessment of conformity, which is printed with this Rulebook as its integral part, and if such body is notified (hereinafter referred to as: Notified Body) in accordance with the law governing technical requirements for products and conformity assessment and the regulation adopted on the basis of that law.

At the request of the manufacturer or his authorised representative, and by his choice, prior to placing it on the market and/put into service, the Notified Body shall carry out, or participate in, the assessment of conformity of apparatus with requirements of this Rulebook, in the manner stipulated in Annex 3 - Conformity assessment carried out by the Notified Body, printed with this Rulebook as its integral part.

The Decision on notification of conformity assessment body as per Paragraph 1 of this Article shall state whether the Notified Body fulfills the requirements for carrying out or participate in the assessment of conformity as per Paragraph 1 (3) of Annex 3 for all apparatus covered by this Rulebook and/or all essential requirements as per Annex 1 and whether the notification is limited to certain aspects of the essential requirements and/or certain types of apparatus.

If the conformity of apparatus as per Paragraphs 2 and 3 has been established, the Notified Body shall issue a Statement certifying the conformity of apparatus.

**Confirmation of Conformity**

**Article 10**

The manufacturer or his authorised representative or importer if the manufacturer or his authorised representative is not established in the Republic of Serbia, prior to placing apparatus on the market shall communicate to the Notified Body original of Declaration of Conformity of that apparatus or certified copy with accompanying technical documentation in accordance with Annex 4 – Technical Documentation and Declaration of Conformity, printed with this Rulebook as its integral part, with a view of certifying the conformity of the apparatus with the requirements of this Rulebook.

If the Notified Body, on the basis of submitted documentation referred to in Paragraph 1 of this Article, establishes conformity of the apparatus, it shall issue the conformation of conformity of such apparatus with the essential requirements stipulated in Annex 1.

Conformation of conformity of apparatus shall contain, in particular: business name or name of the manufacturer; title of this Rulebook and number of the Official Gazette where this Rulebook was published; type of apparatus and designation of the type of apparatus which is the subject of conformity assessment.

Confirmation of conformity referred to in Paragraph 2 of this Article shall be valid for the same type of apparatus of the same manufacturer for the period of three years from the date of issue of this confirmation.

The Notified Body shall keep a record on issued confirmations as per Paragraph 2 of this Article, and shall issue an excerpt from the record upon request by the manufacturer or his authorised representative or importer; the excerpt shall contain, in particular, information on business name of the manufacturer and type of apparatus for which confirmation was issued and its validity period.

The Notified Body shall publish the record on issued confirmations on its official webpage.

Documentation as per Paragraph 1 of this Article does not need to be communicated to the Notified Body for new delivery of apparatus of the same manufacturer and the same type for which confirmation of conformity was issued; and records excerpt referred to in Paragraph 5 of this Article shall be regarded as evidence of validity of issued confirmation.

The manufacturer or his authorised representative shall affix the Serbian conformity mark on the basis of the confirmation of conformity or excerpt from the record issued by the Notified Body.
The Applicant under Paragraph 1 of this Article shall bear costs related to the inspection of documentation and issuance of the confirmation.

Amount of costs referred to in Paragraph 9 of this Article shall be determined by the pricelist of the Notified Body and it shall be proportional to the scope and complexity of documentation to be inspected and time required for conducting such review.

Costs related to issuing of excerpt from the record referred to in Paragraph 5 of this Article may be charged up to the amount of costs necessary for issuing the certificate, which is determined by the pricelist of the Notified Body.

Submission of documentation and acquiring of confirmation of conformity under Paragraphs 2 and 3 of this Article, shall not apply to the manufacturer of apparatus manufactured in the Republic of Serbia and where the Notified Body carried out the assessment of conformity of apparatus in accordance with Annex 3.

Conformity mark

Article 11

Conformity mark shall be affixed on apparatus which is in conformity with the requirements under this Rulebook prior placing it on the market and/or putting into service in the manner specified in Annex 5 – Conformity mark, printed with this Rulebook as its integral part.

The manufacturer, or his authorised representative, or importer if the manufacturer of his representative is not established in the Republic of Serbia, shall affix the conformity so as to be visible, easily legible and indelible, in accordance with the regulation governing the manner of affixing and use of conformity marks.

Other marks, symbols and designations may be affixed on apparatus provided that they do not affect visibility, legibility and/or meaning of the conformity mark.

Marks, symbols and designations whose affixing on apparatus is forbidden by the act governing technical requirements and conformity assessment shall be prohibited to be placed.

If apparatus is subject to other regulations governing other matters, which also provide for the affixing of the conformity mark, affixed conformity mark indicates that the apparatus in question is also presumed to conform to the provisions of those other regulations.

Other indications and information

Article 12

Each apparatus shall be identified in terms of type, batch, serial number or any other information allowing for the identification of the apparatus.

Each apparatus shall be accompanied by documents containing the business name, or name and address of the manufacturer, his authorised representative or of the other person responsible for placing the apparatus on the market.

The manufacturer shall provide information on any specific safety measures that shall be taken when the apparatus is assembled, installed, maintained or used, in order to ensure that, when put into operation the apparatus is in conformity with requirements set out in Appendix 1, Point 1.

A visible indication of the restriction of use shall be placed on apparatus which does not comply to the requirements of protection applying to residential areas, and where appropriate, such indication shall also be placed on the packaging of such apparatus.

The information required to enable apparatus to be used in accordance with the intended use shall be contained in the instructions accompanying the apparatus.

Documentations accompanying apparatus being placed on the market and/or put into service

Article 13

Supplier who places apparatus on the market in the Republic of Serbia shall enclose instructions for use in Serbian language.
In addition to instructions as per Paragraph 1 of this Article, the supplier shall provide original of Declaration of Conformity of apparatus or its certified copy with a translation into Serbian language if the apparatus has not been manufactured in the Republic of Serbia, as well as conformation of conformity, where issued, to accompany the apparatus being placed on the market in the Republic of Serbia.

If the apparatus has not been manufactured in the Republic of Serbia, the supplier who places such apparatus on the market in the Republic of Serbia may make available on its official webpage the original Declaration of Conformity, or a translation thereof into Serbian language, where the webpage address shall be stated in the instructions for use.

V FIXED INSTALLATIONS

Article 14

Apparatus which has been placed on the market and which may be incorporated into a fixed installation is subject to the relevant provisions of this Rulebook.

The application of provisions of Articles 6 and 7 of this Rulebook shall not be compulsory in the case of apparatus which is intended for incorporation into a given fixed installation and is otherwise not commercially available.

The apparatus referred to in Paragraph 2 of this Article shall be accompanied by the documentation describing the fixed installation and its electromagnetic compatibility characteristics, as well as precautions to be taken for the incorporation of the apparatus into the fixed installation in order not to compromise the conformity of that installation with requirements of electromagnetic compatibility.

The accompanying documentation as per Paragraph 3 of this Article shall furthermore include the information referred to in Article 12 (1) and (2) of this Rulebook.

Where there are indications of non-compliance of the fixed installation with requirements for electromagnetic compatibility, in particular, where there are complaints about disturbances being generated by the fixed installation, the owner and/or user of fixed installation is responsible to prove the conformity of such installation and requested proof shall be provided by the Notified Body upon a request of the competent authority.

Where non-compliance of the fixed installation is established, removal of such non-compliance or subsequent ensuring of conformity of such fixed installation with the essential requirements set out in Annex 1, Point 1 shall be provided in accordance with the act governing technical requirements for products and conformity assessment.

VI SAFEGUARD CLAUSE

Supply or use of equipment

Article 15

Supply or use of equipment being placed on the market in the Republic of Serbia, with conformity mark affixed on it, which does not comply with the requirements of this Rulebook, may be limited or prohibited in accordance with the law governing technical requirements for products and conformity assessment.

Conformity with EU regulations

Article 16

VII TRANSITIONAL AND FINAL PROVISIONS

Article 17

From the day when the ratified international agreement on conformity assessment and acceptance of industrial products with the EU comes into force (ACAA agreement), for equipment to which this Rulebook applies, the term: "conformity mark" in Article 1, in the title above Article 11, in Articles 11 and 15 of this Rulebook shall mean: "CE mark", and the term: "Declaration of Conformity" in Articles 1 and 13, as well as in Annex 2, in the title of Annex 4 and in Annex 4 of this Rulebook shall mean: "EC Declaration of conformity".

If the agreement under Paragraph 1 of this Article shall not be concluded, meanings of terms "conformity mark" and "Declaration of Conformity" as per Paragraph 1 of this Article shall apply as from the day of accession of the Republic of Serbia to the European Union.

Article 18

From the day when this Rulebook enters into force till the ratified international agreement on conformity assessment and acceptance of industrial products with the EU enters into force, conformity marking of apparatus, to which this Rulebook applies, shall be performed by affixing the Serbian conformity mark in accordance with this Rulebook and relevant regulations.

If the agreement under Paragraph 1 of this Article shall not be concluded, conformity marking by affixing the Serbian conformity mark shall be performed as from the day of accession of the Republic of Serbia to the European Union.

From the day when the ratified international agreement on conformity assessment and acceptance of industrial products with the EU comes into force (ACAA agreement), conformity marking of apparatus to which this Rulebook applies shall be performed by affixing CE mark in accordance with this Rulebook and relevant regulations.

If the agreement under Paragraph 3 of this Article shall not be concluded, conformity marking by affixing the CE mark shall be performed as from the day of accession of the Republic of Serbia to the European Union.

Article 19

Conformity assessment bodies which are accredited or authorised to carry out assessment of conformity as per regulations under Article 21 (1) of this Rulebook shall issue confirmations of conformity referred to in Article 11 of this Rulebook till their notification in accordance with this Rulebook and relevant regulation.

Article 20

Provisions of Article 10 of this Rulebook shall be repealed as from the day when the ratified international agreement on conformity assessment and acceptance of industrial products with the EU for apparatus to which this Rulebook applies, enters into force.

If the agreement under Paragraph 1 of this Article shall not be concluded, provisions of Article 10 of this Rulebook shall cease to have effect as from the day of accession of the Republic of Serbia to the European Union.

Article 21

Rulebook on mandatory attestation of cable distribution and joint antenna system (Official Gazette of SFRY"", No.37/87) and Rulebook on mandatory attestation of products generating radio-frequency disturbances and conditions that shall be met by enterprises and other legal entities authorised for attesting such products (Official Gazette of SFRY", No.30/91) shall cease to have effect as from the day when this Rulebook enters into force.
Certificate of Conformity issued on the basis of the regulation under Paragraph 1 of this Article shall be repealed as from 1 January 2012.

Article 22

The manufacture or his authorised representative, or importer, may, not later than 1 January 2012, place on the market and/or put into service equipment designed and manufactured and for which conformity was assessed in accordance with requirements under the regulation referred to in Article 21 (1) of this Rulebook.

The conformity document that is issued on the basis of conducted assessment of conformity under Paragraph 1 of this Article or other documents accompanying equipment shall include information of regulations with which equipment is in conformity (title of regulation and number of the Official Gazette where that regulation was published).

Article 23

This Rulebook shall enter into force on the eighth day following its publication in the “Official Gazette of the Republic of Serbia”.

ESSENTIAL REQUIREMENTS FOR ELECTROMAGNETIC COMPATIBILITY

1. General requirements for equipment

Equipment shall be so designed and manufactured, having regard to the state of art, as to ensure that:

1) the electromagnetic disturbances generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended;

2) it has a level of immunity to the electromagnetic disturbances to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use.

2. Specific requirements for fixed installations

A fixed installation shall be installed applying good engineering practices and respecting the information on the intended use of its components, in order to meet protection requirements set out in Point 1 of this Annex. Such good engineering practice shall be documented and the documentation shall be held by the person(s) responsible at the disposal of the relevant authorities for inspection purposes for as long as the fixed installation is in operation.
CONFORMITY ASSESSMENT PROCEDURE CONDUCTED BY THE MANUFACTURER
INTERNAL PRODUCTION CONTROL

1. The manufacturer shall perform the assessment of electromagnetic compatibility of the apparatus, on the basis of the relevant phenomena, with a view to meeting the protection requirements set out in Annex 1 point 1. The apparatus shall be considered meeting requirements regarding electromagnetic compatibility set out in Appendix 1, Point 1 if all relevant harmonised standards stated in the list of standards under Article 7 of this Rulebook have been correctly applied during its design and manufacturing.

2. The electromagnetic compatibility assessment shall take into account all normal intended operating conditions of the apparatus. Where the apparatus is capable of taking different configurations, the electromagnetic compatibility assessment shall confirm whether the apparatus meets the requirements set out in Annex 1, Point 1 in all the possible configurations identified by the manufacturer for its intended use.

3. The manufacturer, in accordance with Annex 4, shall draw up technical documentation providing evidence of the conformity of the apparatus with the essential requirements set out in Annex 1.

4. The manufacturer shall take all necessary measures in order to provide that the apparatus are manufactured in accordance with technical documentation referred to in Point 3 of this Annex and requirements under this Rulebook.

5. The compliance of apparatus with all essential requirements shall be certified by the Declaration of Conformity issued by the manufacturer or his authorised representative.

6. Technical documentation and Declaration of Conformity shall be drawn up in accordance with Annex 4.

7. The manufacturer or his authorised representative shall keep technical documentation and the Declaration of Conformity with a translation into Serbian language if the apparatus has not been manufactured in the Republic of Serbia, at the disposal of the competent authorities for at least 10 years after the date on which such apparatus was last manufactured.

8. If neither the manufacturer nor his authorised representative is established in the Republic of Serbia, the importer of such apparatus in the Republic of Serbia is obliged to keep the Declaration of conformity and technical documentation, as well as to be at the disposal of competent authorities within the period specified under Point 7 of this Annex.
CONFORMITY ASSESSMENT PROCEDURE CONDUCTED BY THE NOTIFIED BODY

The conformity assessment as per this Annex shall be conducted by means of conformity assessment procedure set out in Annex 2 and following additional procedures:

1. The manufacturer or his authorised representative shall communicate the technical documentation to the Notified Body and the application for assessment thereof, specifying which aspects of the essential requirements should be assessed.

2. The Notified Body shall inspect the technical documentation and assess whether the technical documentation demonstrates that the requirements of this Rulebook have been met. If the compliance of the apparatus has been confirmed, the Notified Body shall issue a statement to the manufacturer or his authorised representative confirming the compliance of the apparatus.

3. The statement as per Point 2 of this Annex is limited to aspects of the essential requirements which are assessed by the Notified Body.

The manufacturer or his authorised representative shall enclose the statement referred to in Paragraph 1 of this Point to the technical documentation referred to in Annex 4.
1. Technical documentation

Technical documentation must enable the conformity of the apparatus with the essential requirements to be assessed.

It must include the design and manufacture of the apparatus, in particular:

1) General description of apparatus;

2) The list of Serbian standards applied from the list of standards set out in Article 7 of this Rulebook;

3) Where the manufacturer has not applied Serbian standards from the list of standards set out in Article 7 of this Rulebook, or partially applied them or such standards do not exist, a description and explanation of the procedures applied to meet the essential requirements set out in Annex 1, including a description of the electromagnetic compatibility assessment set out in Annex 2, Point 1, results of design calculations made, examinations carried out, test reports, etc;

4) A statement from the Notified Body, where the conformity assessment procedure referred to in Annex 3 has been conducted.

2. Declaration of Conformity

Declaration of Conformity must contain, in particular:

1) Reference to this Rulebook;

2) Information on identification of the apparatus as set in Article 12 (1) of this Rulebook;

3) Business name, name and address of the manufacturer, and where applicable, business name, or name and address of his authorised representative;

4) Information on the statement of conformity issued by the Notified Body, as well as information on such Body;

5) Place and date of issuing of the Declaration of Conformity;

6) Identity and signature of the authorized person responsible for issuing of the Declaration of conformity on behalf of the manufacturer or his authorised representative.
CONFORMITY MARKS

1. “CE” MARK

CE mark shall consist of the initiated letters “CE” taking the following form:

The CE mark must have a vertical dimension of at least 5 mm.

If the CE mark is reduced and enlarged the proportions given in the above graduated drawing must be respected.

The CE mark must be affixed to the apparatus or to its data plate, where this is not possible or not warranted on account of the nature of the apparatus, it shall be affixed to the packaging, if any, and to the accompanying documents.

2. SERBIAN CONFORMITY MARKS

Serbian conformity mark must consists of three capital letters “A” interconnected in the equilateral triangle (3A), the appearance and content as per the figure below:
Size of the mark must be determined by the height $B$ of the mark which may only have values of standard numbers rounded up, to the order of magnitude $R_{10}$ expressed in millimetres (mm), as per Serbian standard – Standard numbers, numerical values and definitions – SRPS A.A0.001.

The height $B$ of the mark must be, as a rule, at least five millimetres.

The identification number of the Notified, or Authorized conformity assessment body from the Registry of notified or authorized conformity assessment bodies, and the last two digits of the year of issue of the conformity document, if this body performed, or participated in, conformity assessment, must be placed next to the Serbian mark.
CRITERIA TO BE TAKEN INTO ACCOUNT FOR THE NOTIFICATION OF BODIES FOR ASSESSMENT OF CONFORMITY

1. The conformity assessment body, its director, the members of managing board of directors or members of managing board of that body, as well as employees and other involved persons (hereinafter referred to as: staff) responsible for carrying out the assessment of conformity as per this Rulebook must not be the designer, manufacturer, supplier or installer of equipment that they inspect, nor the authorised representative of any of these parties. They must not become involved, either directly or as authorised representatives, in the design, production, marketing or maintenance of the equipment. This does not preclude the possibility of exchanges of technical information between the manufacturer and the Body.

2. The Body referred to in Point 1 of this Annex and its staff shall carry out the assessment of conformity with the highest degree of professional integrity and technical competence and must be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the result of conformity assessment.

3. For each category of equipment for which it is notified, and each conformity assessment procedure, the Body, prior to and after the notification, must possess personnel with technical knowledge and sufficient and appropriate experience to perform a conformity assessment.

   The staff responsible for conducting the assessment of conformity must have:

   1) appropriate experience, and authorisation to perform conformity assessment activities,
   2) qualification and independency in drawing up reports on conducted assessment and perform checks stipulated under this Rulebook.

4. Conformity assessment body must have adequate facilities depending on the requirements laid down in Serbian standards in the List of standards under Article 7 of this Rulebook and type of apparatus which is a subject of conformity assessment, or essential requirements and aspects of such requirements that shall be assessed.

5. The impartiality of staff conducting the assessment must be guaranteed. Their remuneration must not depend on the number of tests carried out or on the results of such tests.

6. The conformity assessment body must possess adequate general act governing basic procedures with regard to conducting conformity assessment activities including decision-making procedure on complaints on the performance of the body and made decisions.

7. The conformity assessment body must have damage liability insurance.

8. The staff of the body must be bound to observe professional secrecy with regard to all information obtained in carrying out procedures for assessing the conformity in accordance with general act on professional secrecy, this Rulebook and other regulations.