

**CE**

: 2001. 4. 18( ) 14:00 - 17:00

: KOTRA (2 )

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**CE**

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## 7. CE marking <sup>(120)</sup>

### 7.1. Principles of CE marking

- The CE marking symbolises the conformity of the product with the applicable Community requirements imposed on the manufacturer.
- The CE marking affixed to products is a declaration by the person responsible that:
  - ➔ the product conforms to all applicable Community provisions, and
  - ➔ the appropriate conformity assessment procedures have been completed.

CE marking symbolises conformity to all the obligations incumbent on manufacturers for the product by virtue of the Community directives providing for its affixing. When affixed to products it is a declaration by the natural or legal person having affixed or been responsible for the affixing of CE marking that the product conforms to all applicable provisions, and that it has been subject to the appropriate conformity assessment procedures. Hence, Member States are not allowed to restrict the placing on the market and putting into service of CE marked products, unless such measures can be justified on the basis of evidence of the non-compliance of the product <sup>(121)</sup>.

### 7.2. Products to be CE marked

- The CE marking is mandatory and must be affixed before any product subject to it is placed on the market and put into service, save where specific directives require otherwise.
- Where products are subject to several directives, which all provide for the affixing of the CE marking, the marking indicates that the products are presumed to conform to the provisions of all these directives.
- A product may not be CE marked, unless it is covered by a directive providing for its affixing.

The obligation to affix the CE marking extends to all products within the scope of directives providing for its affixing, and which are intended for the Community market <sup>(124)</sup>. Thus, the CE marking must be affixed:

- to all new products, whether manufactured in the Member States or in third countries;
- to used and second-hand products imported from third countries; and

The directives providing for the affixing of the CE marking mostly follow the principles of the New Approach and the Global Approach, but this is in itself irrelevant for the application of the CE marking. In fact, CE marking can be introduced in Community legislation as legal conformity marking if:

- the method of total harmonisation is used, which means that diverging national regulations that cover the same public interests as the directive are prohibited; and

- the directive contains conformity assessment procedures according to Decision 93/465/EEC <sup>(122)</sup>.

As a general rule, all New Approach directives provide for the affixing of the CE marking. In duly justified cases a total harmonisation directive that follows Decision 93/465/EEC may provide for a different marking instead of the CE marking <sup>(123)</sup>.

Since all products covered by New Approach directives bear CE marking, this marking is not intended to serve commercial purposes. Neither is the CE marking a mark of origin, as it does not indicate that the product was manufactured in the Community.

- to substantially modified products that are subject to directives as new products.

Directives may exclude the application of the CE marking on certain products, even if the directive otherwise applies to the product. As a general rule, such products are subject to free circulation <sup>(125)</sup>, if:

- they are accompanied by a declaration of conformity (as is the case for safety components referred to in the Directive on machinery and partly completed boats referred to in the Directive on recreational craft);
- they are accompanied by a declaration of compliance (as is the case for products playing a minor part with respect to the health and safety listed in accordance with the Directive on construction products);
- they are accompanied by a statement (as is the case for custom-made medical devices and devices intended for clinical investigations referred to in the Directives on active implantable medical devices and medical devices, and devices intended for performance evaluation referred to in the Directive on *in vitro* diagnostic medical devices);

<sup>(120)</sup> This Chapter does not apply to the Directive on the high-speed rail system.

<sup>(121)</sup> For market surveillance, see Chapter 8.

<sup>(122)</sup> Conformity assessment according to the Directive relating to construction products does not follow Decision 93/465/EEC. However, this Directive provides for the CE marking.

<sup>(123)</sup> The Directive on marine equipment does not provide for a CE marking, but instead for a special conformity mark to which the guidelines of this chapter generally apply.

<sup>(124)</sup> For products submitted to directives, see Section 2.1.

<sup>(125)</sup> In addition, the Directive on pressure equipment entitles Member States to authorise, on their territory, the placing on the market and the putting into service by users, of pressure equipment or assemblies not bearing the CE marking, but that have been subject to a conformity assessment carried out by a user inspectorate instead of a notified body.

- they are accompanied by a certificate of conformity (as is the case for components referred to in the Directive relating to potentially explosive atmospheres which are intended to be incorporated into equipment or protective systems, and fittings referred to in the Directive relating to gas appliances);
- the product bears the manufacturer's name and an indication of maximum capacity (as is the case for instruments not subject to conformity assessment according to the Directive relating to non-automatic weighing instruments); or
- the product is manufactured in accordance with sound

The manufacturer, whether established inside or outside the Community, is the person ultimately responsible for the conformity of the product with the provisions of the directive and for the affixing of the CE marking. The manufacturer may appoint an authorised representative established in the Community to act on his behalf. The person responsible for placing the product on the market may, exceptionally, be deemed to have assumed the responsibilities of the manufacturer <sup>(127)</sup>.

The CE marking may not, in principle, be affixed until the conformity assessment procedure has been completed to ensure that the product complies with all the provisions of the relevant directives. This will usually be at the end of the production phase. This poses no problem if, for example, the CE marking is on a data plate that is not affixed to the product until after the final inspection. However, if the CE marking forms an inseparable part of the product, or of a component, for example by stamping or casting, the marking can be affixed at any other stage of the production phase, provided that the conformity of the product is verified as appropriate throughout the production phase.

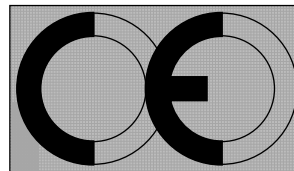
The CE marking shall, as a rule, be affixed to the product or to its data plate. In addition, it can be affixed, for instance, to the packaging or to the accompanying documents. However, it may exceptionally be moved from the product or its data plate if this rule cannot be followed. This would be justified where affixing it to the product was impossible (for example on certain types of explosives), or not possible under reasonable technical or economic conditions, or where the minimum dimensions could not be respected, or it could not be ensured that the CE marking was visibly, legibly and indelibly affixed. In such cases, the CE marking has to be affixed to the packaging, if it exists, and to the accompanying document, where the directive concerned provides for such docu-

engineering practice (as is the case for certain vessels referred to in the Directives relating to simple pressure vessels and pressure equipment).

During the transitional period of a directive the manufacturer usually has the choice to either meet the requirements of the directive or the relevant national regulations. The option chosen and, hence, the extent of the conformity expression enshrined in the CE marking shall be clarified by the manufacturer in the EC declaration of conformity, and in the documents, notices or instructions accompanying the product <sup>(126)</sup>.

### 7.3. Affixing of the CE marking

- **The CE marking must be affixed by the manufacturer, or by the authorised representative established within the Community.**
- **The CE marking must take the form below. If the CE marking is reduced or enlarged the proportions must be respected.**



- **The CE marking must be affixed visibly, legibly and indelibly to the product or to its data plate. However, where this is not possible or not warranted on account of the nature of the product, it must be affixed to the packaging, if any, and to the accompanying documents, where the directive concerned provides for such documents.**
- **Where a notified body is involved in the production control phase according to the applicable directives, its identification number must follow the CE marking. The manufacturer or the authorised representative established in the Community affixes the identification number, under the responsibility of the notified body.**

ments. The CE marking on the product may neither be omitted nor be moved to the packaging or accompanying documents on purely aesthetic grounds <sup>(128)</sup>.

The CE marking symbolises conformity to essential public interests covered by the directives in question. Therefore, it is to be considered as essential information to Member States' authorities as well as other relevant parties (for example distributors, consumers and other users). Accordingly, the requirement for visibility means that the CE marking must be easily accessible for all parties. It could, for instance, be affixed on the back or underside of a product. A minimum height of 5 mm is required to ensure that it is legible <sup>(129)</sup>. It shall also

<sup>(126)</sup> For the transitional period, see Section 2.4.  
<sup>(127)</sup> See Sections 3.1 – 3.3.

<sup>(128)</sup> The provisions regarding the affixing of the CE marking vary between directives; in some sectors they are more stringent (see for instance Directives relating to simple pressure vessels, machinery, non-automatic weighing instruments, active implantable medical devices, gas appliances, medical devices, telecommunications terminal equipment, hot-water boilers, recreational craft (as regards boats), lifts, potentially explosive atmospheres, refrigeration appliances, pressure equipment, in vitro diagnostic medical devices, and radio and telecommunications terminal equipment), and in other sectors more flexible (see for instance Directives relating to low voltage equipment, toys, construction products and electromagnetic compatibility).  
<sup>(129)</sup> According to the Directives relating to machinery, personal protective equipment, active implantable medical devices, medical devices, potentially explosives atmospheres, lifts (as regards safety components), in vitro diagnostic medical devices, and radio and telecommunications terminal equipment the minimum dimension of the CE marking may be waived for small devices. The same applies to the conformity mark provided for in the Directive on marine equipment.

be indelible so that it cannot be removed under normal circumstances without leaving noticeable traces (for example some product standards use a rub test with water and petroleum spirits). However, this does not mean that the CE marking must form an integral part of the product.

A notified body may be involved in the design phase, the production phase, or both, depending on the conformity assessment procedures applied <sup>(130)</sup>. The CE marking shall only be followed by the identification number of the notified body if it is involved in the production phase. Thus, the identification number of a notified body involved in conformity assessment according to module B does not follow the CE marking. Sometimes several notified bodies are involved in the production phase, which is possible where more than one directive is applicable. In these situations several identification numbers follow the CE marking.

Thus, the CE marking may appear on products either:

- *without* an identification number, which means that a notified body did not intervene in the production phase (module A, modules Aa1 and Cbis1 where the notified body only intervened during the design phase, and the combination of modules B and C); or
- *with* an identification number, which means that the notified body assumes the responsibility:

- for the tests on specific aspects of the product (modules Aa1 and Cbis1 where the notified body intervened during the production phase);
- for product checks (modules Aa2 and Cbis2);
- for the examinations and tests carried out to assess the conformity of the product during the production control phase (modules F, Fbis and G); or
- for the assessment of production, product quality assurance or full quality assurance (modules D, E, H and their variants).

The CE marking and the identification number of the notified body do not necessarily have to be affixed within the Community. They may be affixed in a third country, for example if the product is manufactured there and the notified body carried out conformity assessment in accordance with the directive in that country. The CE marking and the identification number can also be affixed separately, as long as they remain combined.

The CE marking consists exclusively of the letters ‘CE’ followed by the identification numbers of any notified body involved in the production phase. Pictograms or other marks indicating, for instance, the category of use are, according to some New Approach directives, complementary to the CE marking but do not form part of it <sup>(131)</sup>.

## 7.4. CE marking and other marks

● **CE marking is the only marking which symbolises conformity to all the obligations incumbent on manufacturers for the product as required by the applicable directives providing for its affixing. Member States shall refrain from introducing any reference to another conformity marking into their national regulations, which would signify conformity with objectives that relate to the CE marking.**

● **A product may bear additional markings and marks, provided that they:**

- ➔ **fulfil a different function from that of the CE marking,**
- ➔ **are not liable to cause confusion with it, and**
- ➔ **do not reduce its legibility and visibility.**

The CE marking replaces all mandatory conformity markings having the same meaning, which existed before harmonisation took place. Such national conformity markings are incompatible with CE marking and would constitute an infringement of the applicable New Approach directives. When transposing the directives, Member States shall incorporate the CE marking in their national regulations and administrative procedures. They shall also refrain from introducing any other conformity marking into their national legislation that has the same meaning as the CE marking.

Owners of trademarks similar to the CE marking, that were acquired before the introduction of the CE marking, will be protected against expropriation since such marks will, as a rule, not be liable to deceive market surveillance authorities, distributors, users, consumers or other third parties.

In view of the objectives of technical harmonisation, markings and marks additional to the CE marking need to fulfil a different function from that of the CE marking. Thus, they should provide an added value in signifying conformity with objectives that are different from those to which the CE marking relates (for example environmental aspects not covered by applicable directives).

The affixing of legal marking (such as a protected trademark of a manufacturer), or of acceptable certification and other marks additional to the CE marking, is allowed to the extent that such markings or marks do not create confusion with the CE marking, and that they do not reduce the legibility and visibility of the CE marking. This confusion may either refer to the meaning or form of the CE marking <sup>(132)</sup>. Whether or not a marking or mark is confusing should be decided from the point of view of all relevant parties likely to come into contact with it.

<sup>(130)</sup> See Section 5.1 and Annex 7.

<sup>(131)</sup> For instance, the symbol to indicate that telecommunications terminal equipment is suitable for connection to the public telecommunications network, the energy performance label required for hot-water boilers, the explosion protection symbol required for equipment and protective systems intended for use in potentially explosive atmospheres, or the equipment class identifier required for radio equipment. Some directives also require that the last digits of the year in which the CE marking was affixed is indicated.

<sup>(132)</sup> The wording used in various New Approach directives varies slightly, but any other interpretation would prevent achieving the purpose of the applicable provisions.





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- : 6,023,355 (57.2%)
- : 4,503,530 (42.8%)

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- UL : 3.5
- QS-9000 : 6.8 ( )

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(Single European Act) (White Paper) 1992 EU  
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 1985  
 EU New Approach(  
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 CENELEC, CEN, ETSI  
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 Norm HD : Harmonized Documents ENV :  
 EuropeanPre- Standards ) 3000 .  
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 1990 12 가  
 가 (Global Approach)  
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 (EOTC: European Organization  
 for Testing and Certification) (1990. 4. 25) EU  
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- 1~2 .
- 1 , 5000 .
- 가 Spec .

- T.C.F 10 .
- CE 가 .
- 가 .
- CE .

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- ISO 9000, ISO 14000
- QS-9000 : (
- TL-9000 : (QuEST Forum)
- HACCP :

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- UL :
- ENEC 5 : ( )
- CSA :
- CCIB : ( )
- FCC :
- FDA : ( , , , )
- GOST : 가

ISOBank.com

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Mock - up

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70% , 30%

**CE**

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## LVD Directive

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- TEL:031-746-8500, FAX:031-746-8700
- Email :sshong@onetech.co.kr



## LVD Directive ?

- Electrical equipment : 50-1,000 Vac 75-1,500 Vdc
- 73/23/EEC 93/8/EEC
- EMC Directive ,



## LVD

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- EU

## EU

- Notified Body :
- CENELEC :
- DOC : Declaration of Conformity :  
(test )
- COC : Certificate of Conformity :  
가

## Technical Documentation

- 
- 가
- Competent Authority가
- 10

## Technical Documentation

- A general description of the electric equipment
- design and manufacture drawings plus diagrams of components, subassemblies, circuits, etc.
- description and explanations needed to understand the above mentioned drawings and diagrams plus the operation of the electric equipment

- A list of the standards used, in full or in part, and a description of the solutions employed to meet the safety aspects of this directive when standards have not been applied
- the results of design calculations and of checks carried out, etc.
- test report (the manufacturer or third party)

- LVD (EN 60950) : -  
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PCB pattern , Ventilation Opening,  
edge, Transformer , sharp  
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- Cap.  
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(Limited current circuit)

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(leakage current)

(abnormal)

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가 (laser ..)

- (ITE) : EN 60950, EN41003
- Audio & Video : EN 60065
- 가 : EN 60335-1
- 가 : EN 60335-2-6(Particular requirements for stationary cooking ranges, hobs, ovens)

- 가 : EN 60335-2-6  
(Particular requirements for cooking ranges, cooking tables, ovens and similar appliances)
- EN 60335-2-8 (Particular requirements for electric shavers, hair clippers and similar appliances)

- EN 60335-2-9 (Particular requirements for grills, toasters and similar portable cooking appliances)
- UPS : EN50091-1
- Laser : EN 60825
- : EN 61010

## EU

- EU home page:  
[http://europa.eu.int/comm/enterprise/electr\\_equipment/index.htm](http://europa.eu.int/comm/enterprise/electr_equipment/index.htm)
- EU :
  - EN : European Standard
  - ENV : European Prestandard
  - ETSI : European Telecommunication Standard Institute

- ( )
  - HD : Harmonization Document
  - prEN : draft European Standard
  - prENV : draft European Prestandard
  - prHD :draft Harmonization Document
  - dow : latest date of withdrawal of conflicting national standard
  - doa : latest date of announcement of the new EN/ENV/HD at national level

- ( )
  - dop : latest date of publication of identical/ a harmonized national standard
  - SC : Subcommittee
  - WG : Working Group

# EMC Directive-89/336/EEC.

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EMC

EMC

**Basic Concept**

**European EMC Standards**

**Directive 89/336/EEC**

**Approvals Procedure**

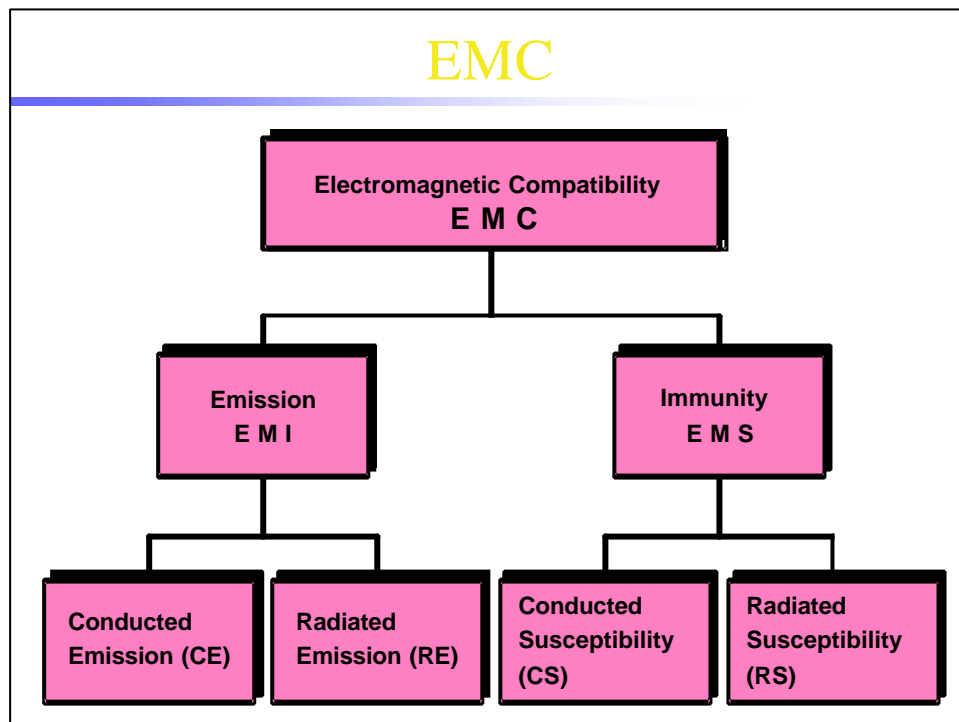
**Guidlines on the Application of 89/336/EEC**

**Directive 99/5/EC (R&TTE)**

**Application assessment procedure**



## EMC

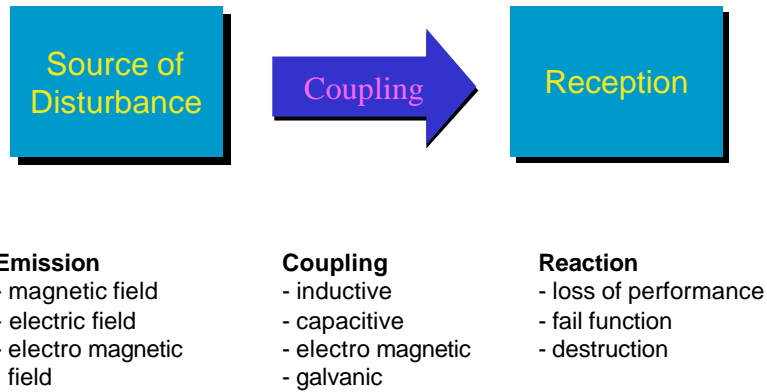


## EMC

- **Electromagnetic Compatibility (EMC) means**
  - the ability of apparatus to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbance to other apparatus in that environment.

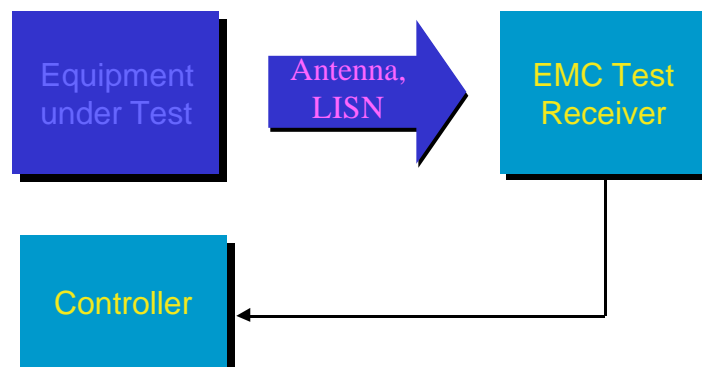
## Basic Concept

- **EMC Model**



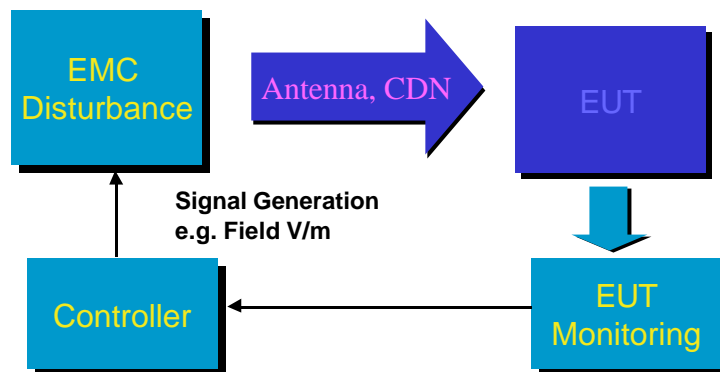
- **Emission**

- Conducted Emission, Harmonic, Flicker
- Radiated Emission



- **Immunity**

- ESD
- Conducted Immunity (Burst, Surge, C.S, Voltage Dip etc.)
- Radiated Immunity (R.S., Magnetic etc)



## European EMC Standards

- **Depending on their origin European EMC Standards are assigned to one of three number groups**

- |           |               |                                  |
|-----------|---------------|----------------------------------|
| - CENELEC | EN 50 000 + x | eg EN 50 081                     |
| - CISPR   | EN 55 000 + x | eg EN 55 013 (based on CISPR 13) |
| - IEC     | EN 60 000 + x | eg EN 61000 (based on IEC 1000)  |

- **EMC standards are divided into the following three types**

- |                    |                                  |
|--------------------|----------------------------------|
| - Basic Standard   | eg CISPR 16, IEC 1000 (EN 61000) |
| - Generic Standard | eg EN 50082                      |
| - Product standard | eg EN 55013/55020                |

## Directive 89/336/EEC

### **COUNCIL DIRECTIVE OF 3 MAY 1989 ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES RELATING TO ELECTROMAGNETIC COMPATIBILITY (89/336/EEC)**

(23.5.89 OJ No L 139/19)

Short name: [EMC]

Base: Directive 89/336/EEC

Modification: Directive 92/31/EEC [ ]

Directive 93/68/EEC [CE Marking]

Directive 91/263/EEC [TTE] &

Directive 93/97/EEC [Satellite]

Application: Guidelines on the application of

Guide Council Directive 89/336/EEC

(Modification for publication in November 1997)

## Directive 89/336/EEC

### • **Objective of the EMC Directive**

- to guarantee the free movement of **apparatus**
- to create an acceptable electromagnetic environment in the EEA territory
- apparatus:  
all electrical and electronic appliances together with equipment and installations containing electrical and/or electronic components
- The protection objective of the EMC directive is to ensure that the functioning of apparatus is not degraded by an electromagnetic phenomenon


signals considered **do not include** the signals wanted and **required** for the use of the apparatus

## Directive 89/336/EEC

- **Important articles**

- **Article 2 : Scope**
- **Article 4 : EMC requirements: Emission and Immunity**
- **Article 7 : Harmonized standards (published in official journal) provided by CENELEC and ETSI**
- **Article 9 : Enforcement (withdraw apparatus etc.)**

## Approvals Procedure



Radio transmitter

## Approvals Procedure

### ● Procedure in accordance with Article 10.2

- requires a competent body (not a notified body) but manufacturer chooses what assessment he requires from the competent body in order to complete the technical construction file
- Responsibility still by the manufacturer !
- Technical Construcion File
  - general description of the product
  - design an manufacturing drawings
  - description and explanations needed ... as well as the operational aspects of the product
  - list of standards applied in whole or in part and a description of the solutions adopted in ordewr to comply with the protection requirements ... in cases where the standards have not been applied
  - design calculation results arising from the EMC tests
  - report or certificate by the competent body
  - a copy of the instruction for use

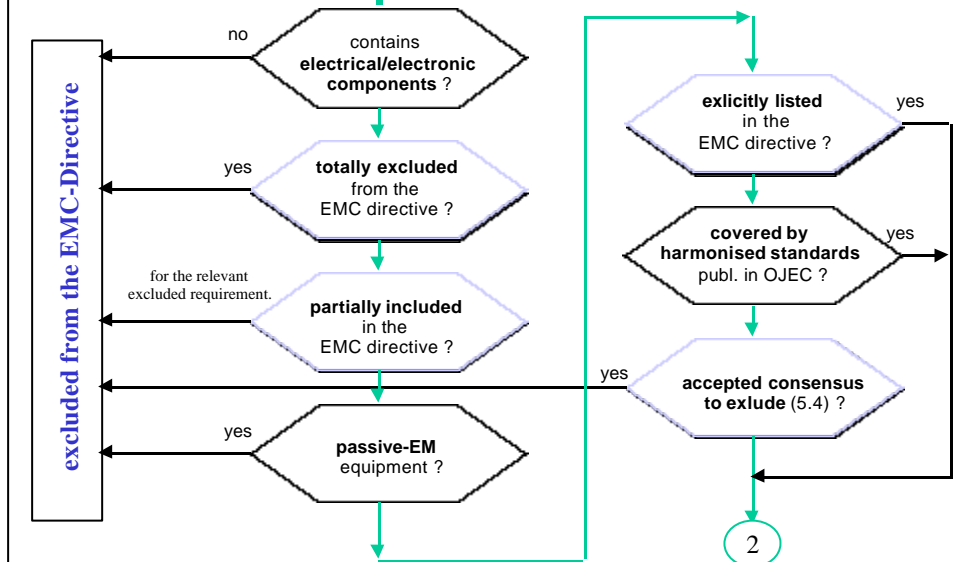
## Approvals Procedure

### ● Procedure in accordance with Article 10.5

- only applicable to apparatus designed for the [transmission of radio communications](#) (as defined in the ITU Convention)
- requires a [notified body](#) choosed by the manufacturer
- is a **type examination** (EC Type Examination Certificate)
- Application for type examination include
  - name and address of the manufacturer or his authorised representativ
  - a written declaration that the same application has not been lodged with any other notified body
  - technical documentation
- It is not valid any more acc. to [New R&TTE Directive](#)

## Guidelines on the Application of 89/336/EEC

### • Decision Flow Chart (1)



## Guidelines on the Application of 89/336/EEC

### • Totally Excluded

- **Radio equipment used by radio amateurs** unless the apparatus is available commercially
- **Motor vehicles** (covered by specific Directive 90/385/EEC)
- **Active implantable medical devices** (covered by specific Directive 90/385/EEC)
- **Medical devices** (covered by specific Directive 93/42/EEC) <sup>1)</sup>
- **In vitro Diagnostic Medical Devices** (proposal for a Directive)
- **Equipment intended for use in aircraft in flight** (covered by Council Regulation EEC No 3922/91)
- **Marine equipment:** if covered by specific Directive 96/98/EC <sup>2)</sup>

<sup>1)</sup> transitional period ending 14 June 1998

<sup>2)</sup> transitional period ending 31 December 1998

## Guidlines on the Application of 89/336/EEC

- **Partially Included**

- Non-automatic weighing instruments :  
only emission requirements are covered, immunity by Annex I-8(2) of 90/384/EEC
- Agricultural and forestry tractors :  
only immunity covered, The emission requirements are covered by Directive 75/322/EEC

## Guidlines on the Application of 89/336/EEC

- **Explicitly Listed:**

- Electrical household appliances, portable tools and similar equipment
- Fluorescent lighting luminaires fitted with starters
- Fluorescent lamps
- Industrial manufacturing equipment
- Information technology equipment
- Domestic radio and television receivers
- Radio and television broadcast transmitters
- Aeronautical and marine radio apparatus
- Educational electronic equipment
- Amateur radio equipment if commercially available
- Telecommunications apparatus
- Radio communication transmitters (incl. CB, walkie-talkies etc)
- Radio communication receivers



## Guidelines on the Application of 89/336/EEC

- **Accepted consensus to exclude:**

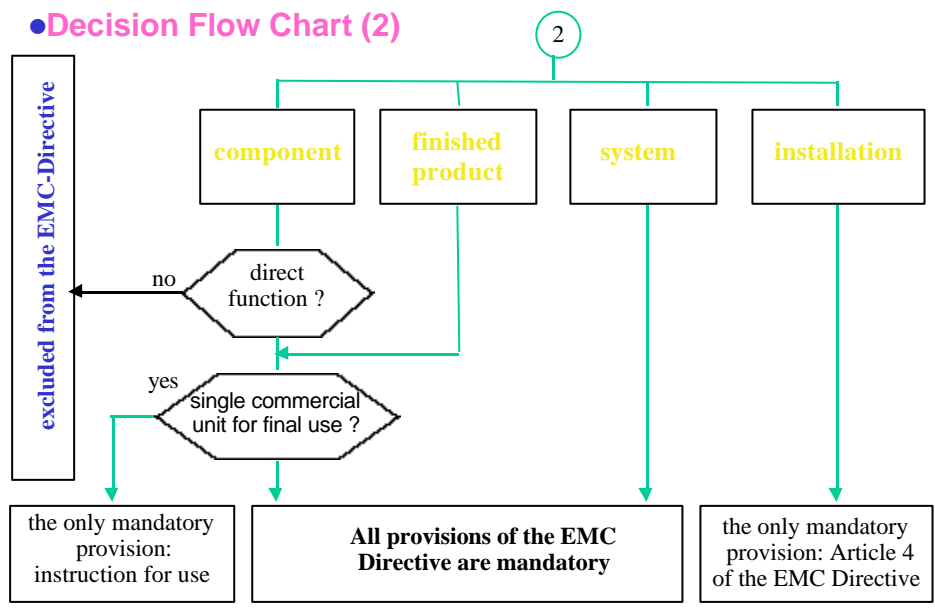
- The emission level is by the inherent nature of the physical characteristics and mode of operation far below the most stringent limits of the relevant EMC standards
- With regard to immunity experience shows that such apparatus does function satisfactorily by the inherent nature of physical characteristics...

- **Examples**

- fuses, circuit breakers without electronic parts which are EM active
- Manual switches which do not contain any components which are EM active
- High voltage inductors and transformers
- Capacitors
- Induction motors
- Quarz wrist watches without additional functions (eg radio receivers)
- Filament lamps (bulbs)

## Guidelines on the Application of 89/336/EEC

- **Decision Flow Chart (2)**



## Guidelines on the Application of 89/336/EEC

- **Component**

- with **direct function**  
(eg plug-in cards for computer systems, electronic mail cards, programmable logic control, computer disk drives)
- without direct function  
(eg resistors, capacitors, coils, diodes, transistors, integrated circuits, cables, all or nothing relays, plugs, sockets)

- **direct function**

- any function of the component itself which fulfills the intended use specified by the manufacturer in the instruction for use for an end-user
- ... this function has to be available without further adjustment or connections other than simple ones which can be performed by any person not fully aware of the EMC implications

## Guidelines on the Application of 89/336/EEC

- **Finished Product**

- has a direct function
- has an enclosure of its own
- if applicable: ports and connections intended for end users

- **System**

- components, finished products combined, designed and/or put together by the same person .... as a single functional unit ...installed and operated together to perform a specific task

- **Installation**

- fixed installations: a combination of several parts assembled and/or erected ... *at a given place*...
- movable installations

## Guidlines on the Application of 89/336/EEC



(CE mark of conformity for all products except radio telecommunications equipment and telecommunications terminal equipment)

- Compliance with the requirements of the EMC Directive is shown by the CE mark, affixed to the apparatus. Basis for CE marking is the EC declaration, issued by the manufacturer or importer, which has to be held at the disposal of the competent authority for ten years.

**The CE mark is never awarded to a product by an official body but is always affixed to the equipment under the full responsibility of the manufacturer or importer of the product**

## Directive 99/5/EC (R&TTE)

### **Directive 99/5/EC**

**of the European Parliament and of the Council of 9 March 1999  
on radio equipment and telecommunications terminal equipment and the  
mutual recognition of their conformity  
(Official journal 07/04/1999 No. L 91/10)**

Short name: **RTTE**

Base: 99/5/EC

directive

repealed      Directive **98/13/EC** and 10(5) of 89/336/EEC  
(from 8. Apr. 2000)

## Directive 99/5/EC (R&TTE)

- **Important articles:**

- **Article 1** : **Scope and aim**
- **Article 3** : **Essential requirements**
- **Article 5** : **Harmonised standards**
- **Article 10** : **Conformity assessment procedures**
  - **10.3 TTE Equipment** not using radio spectrum
  - **10.4 Radio Equipment** (harmonised standards applied)
  - **10.5 Radio Equipment** (harmonised standards not/ partly applied)

## Directive 99/5/EC (R&TTE)

- **Terminal Equipment**

- equipment **enabling communication** intended to be **connected to** interfaces of **public telecommunications network**

- **Radio Equipment**

- equipment capable of communication by means of **emission and/or reception of radio waves**
- **9 kHz to 3000 GHz**

## Directive 99/5/EC (R&TTE)

- **Equipment not covered by the present directive (Article 1.5)**
  - Apparatus exclusively used for activities concerning **public security, defence, State security** and activities of the State in **areas of criminal law**
- **Equipment not covered by the present directive (Article 1.4, Annex I)**
  - **Radio equipment used by radio amateurs**  
unless the equipment is available commercially
  - **Marine equipment**  
if covered by specific Directive 96/98/EC
  - **cabling and wiring**
  - **Air-traffic-management equipment and systems**  
covered Directive 93/65/EEC
  - **Equipment intended for use in aircraft in flight**  
covered by Council Regulation EEC No 3922/91

## Directive 99/5/EC (R&TTE)

- **Essential Requirements**
  - The objectives contained in 73/23/EEC (**LVD**) with respect to **safety requirements**, but with no lower voltage applying
  - The protection requirements contained in 89/336/EEC(**EMC**) with respect to **electromagnetic compatibility**
  - **Interactions** via networks with other apparatus (3.3.a)
  - **Prevention of harm to network** or its functioning, causing an unacceptable degradation of service other than the user of the effective use of spectrum (3.3.b)
  - **Privacy of user** (3.3.c)
  - **Avoidance of fraud** (3.3.d)
  - **Access to emergency services** (3.3.e)
  - **Use by users with disability** (3.3.f)

## Application assessment procedure

Type of Equipment	Compliance Routes			
	Annex II - Internal Production Control	Annex III - Internal Production Control + Radio testing	Annex IV - Technical Construction File	Annex V - Full Quality Assurance
Wired Telecommunications Terminal Equipment	★		★	★
Receiver parts of Radio Equipment	★		★	★
Radio Equipment to which harmonized standards are applicable		★	★	★
Radio Equipment to which harmonized standards are NOT applicable or apply partially			★	★

## Application assessment procedure

### • Annex II

- **Internal production control**
- **Technical Documentation**
  - general description of the product
  - design and manufacturing drawings
  - description and explanations needed ... as well as the operational aspects of the product
  - **list of standards applied in whole or in part and a description of the solutions adopted in order to comply with the protection requirements ... in cases where the standards have not been applied**
  - design calculation results, examinations carried out, etc
  - test reports
- **manufacturing process** ensures compliance of the ... product with the technical documentation and with the requirement of this Directive...

## Application assessment procedure

- **Annex III**

- **Internal Production Control**

- = Internal production control (Annex II) + specific Apparatus tests

For each type of Apparatus, all essential **radio test suites** must be carried out by the manufacturer or on his behalf.

The identification of test suites ... is the responsibility of a **notified body** ... [except](#) where the test suites are defined in the harmonized standards

The manufacturer .. shall declare that these tests have been carried out and that the Apparatus conforms to the tests and shall **affix the notified body's identification number** ...

- **Annex IV**

- **Technical Construction File (TCF)**

- = Technical Documentation (Annex II) + specific radio test suites (Annex III)  
present the TCF to notified body

## Application assessment procedure

- **Annex V**

- **Full Quality Assurance**

- Manufacturer Declaration
    - approved quality system for design, manufacture and final product inspection and testing
    - Quality system
    - Notified body assesses and approves the Quality system
    - Manufacturer fulfills the obligations arising out of the approved quality system  
Manufacturer keep the notified body informed of any intended updating of the quality system
    - Manufacturer allows access for inspection, audits, unexpected visits of the notified body

**CE :**

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## 4.

### 4.1

- 
- 
- 
- ( , )
- ( , )
- 
- :
- , , ,

## 4.

### 4.2

- 
- EN, IEC

### 4.3

- :  $0.9 V_r - 1.1 V_r$
- :  $0.99 F_r - 1.01 F_r$
- Harmonics : 10% of  $V_{rms}$  (2, ..., 5)
- Impulse : Duration 1.5 ms

## 4.

: Rise/Fall : 500 ns 500  $\mu$ s

Magnitude :  $2 V_{rms}$

- Interruption : 3 ms

### 4.4 (Physical environment and operating conditions)

#### 4.4.1

B

#### 4.4.2 EMC

EMC ; Emission - Industrial : EN 50081-2

EMC ; Immunity - Industrial : EN 50082-2

EMC ; Electrostatic discharge

## 4.

4.4.3 (Ambient air temperature):  
+5 - +40

4.4.4 (Humidity): +40 , 50%

4.4.5 (Altitude): 1000 m

4.4.6 (Contaminants): 12.3

## 4.

4.4.7 (Ionizing and non-ionizing radiation)  
• Microwave, Ultraviolet, Lasers, X-rays

4.4.8 / (Vibration, shock and bump)  
• /

4.5 (Transportation and storage)  
• : (-25 +55 ), (24 h +70 )  
• , ,

## 4.

### 4.6 (Provisions for Handling)

- ,

### 4.7 (Installation and operation)

- 
- 


## 5. (Incoming supply conductor terminations)

### 5.1 (Incoming supply conductor terminations)

- - Plug  
- Supply disconnecting  
- Terminal Block
- "N"
- Enclosure
- (L1, L2, L3, PE)

## 5. (Incoming supply conductor terminations)

5.2 (Terminal for connection  
to the external protective earthing system)

- =  
(ex. 1.2 mm<sup>2</sup> 가  
1.2 mm<sup>2</sup> .)
- : "PE"
- Bonding conductor :  
 or GREEN-AND-YELLOW

## 5. (Incoming supply conductor terminations)

5.3 (Supply disconnecting device)

5.3.1

- ( , , 3 )
- , Interlock

## 5. (Incoming supply conductor terminations)

### 5.3.2 (Type)

- - a) (Switch-disconnector): EN 60947-3
  - b) (Disconnecter): Fuse , EN 60947-3
  - c) (Circuit breaker): EN 60947-2
  - d) Plug/Socket : 16 A, 3 kW
  - e) 가
    - :
    - Plug/Socket
    - Plug/Socket IP2X

## 5. (Incoming supply conductor terminations)

### 5.3.3 (Requirements)

- : OFF (0), ON (1)
- OFF
- : Black or Gray ( , Emergency stop device=Red)
- OFF eg. Pad locks
- ( , TN )
- (Breaking capacity) +
- Motor

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## 5. (Incoming supply conductor terminations)

### 5.3.4 (Operating handle) :

- - 0.6 m - 1.9 m
  - : 1.7 m
- 

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## 5. (Incoming supply conductor terminations)

### 5.3.5 (Excepted circuits) :

- - plus/socket
  - (under voltage)
  - 가
  - : (e.g. , , )
  - ( , 가 )
  - Warning Label
  - Warning Label
  - Maintenance manual
-

## 5. (Incoming supply conductor terminations)

5.4 (Devices for  
Switching off for prevention of unexpected start-up)

- 가 OK
- 
- &

5.5 (Devices for disconnecting  
electrical equipment)

- 
- 5.3

## 5. (Incoming supply conductor terminations)

5.6 (Protection against unauthorized,  
inadvertent and/or mistaken connection)

- 5.4 5.5 가
- Fuse  
가



## 6. (Protection against electric shock)

- 6.1 (General)
- (Direct Contact)
  - (Indirect Contact)

### 6.2 (Protection against direct contact)

#### 6.2.1

- 가 :
- IP4X

## 6. (Protection against electric shock)

### 6.2.2 Enclosure (Protection by enclosures)

( 1 )

- Enclosure Key or Tool

- Enclosure ( ) : IP2X

가

## 6. (Protection against electric shock)

( 2 )

- Enclosure가 open      Enclosure  
(e.g. Door - interlocking  
disconnecter)

- 가

IP2X

Warning sign:



## 6. (Protection against electric shock)

### 6.2.3

(Protection by insulation of live parts)

- 
- .
- : , , ,
- :

Paints, Varnishes, Lacquers,

## 6. (Protection against electric shock)

### 6.2.4

(Protection against residual voltages) :

- 5 60 V :
- ( 60 V )
- 60  $\mu$ C
- 가 Warning sign
- Plug 1 60 V
- IP2X

## 6. (Protection against electric shock)

### 6.2.5

(Protection by barriers) :

- IEC 60364-4-41 412.2

### 6.2.6

(Protection by placing out of reach or protection by obstacles)

- IP2X

## 6. (Protection against electric shock)

### 6.3 (Protection against indirect contact)

#### 6.3.1

- - ,
  -

## 6. (Protection against electric shock)

### 6.3.2 (Measures to prevent the occurrence of a hazardous touch voltage)

- Class II
- :
- :

## 6. (Protection against electric shock)

### 6.3.3 (Protection by automatic disconnection of supply) :

- Touch voltage
  - 
  -

## 6. (Protection against electric shock)

### 6.4 (Protection by the use of PELV)

PELV : Protective Extra Low Voltage

#### 6.4.1

- - a) 25 Vac                      60 Vdc
  - b)
  - c) PELV
  - d) PELV
  - e) PELV                      Plug/Socket
    - Plug
    - Socket                      Plug기

## 6. (Protection against electric shock)

### 6.4.2 PELV

- - 1, 2
  - 1, 2
  - (
  - )
  - 6.4.1

## 7. (Protection of equipments)

### 7.1 (General)

- 
- 
- 
- 
-

## 7. (Protection of equipments)

### 7.2 (Overcurrent protection)

#### 7.2.1

- 

#### 7.2.2 (Supply conductors) :

- 

가

- , Installation diagram
- 

## 7. (Protection of equipments)

### 7.2.3 (Power circuits)

- 

- 

- IT

- ,
-

## 7. (Protection of equipments)

### 7.2.4. (Control circuits) :

- 
- 2

## 7. (Protection of equipments)

### 7.2.5 Socket outlet (Socket outlets and their associated conductors)

- Socket outlet
- 

### 7.2.6 (Local lighting circuits)

- 

( )



### 7.2.7

### 7.2.8

●

- 

•

•

## 7. (Protection of equipments)

### 7.2.9

(Overcurrent protective Devices) :

- (Breaking capacity)
- (7.2.1 )  
가
- Fuse Circuit-  
breaker
- 가
- Fuse 가 가

## 7. (Protection of equipments)

### 7.2.10 (Rating and setting of overcurrent protective devices) :

- Fuse (e.g , )
-

## 7. (Protection of equipments)

### 7.3 (Overload protection of motors)

- 0.5 kW
- 
- (Overload protective devices)
- (Temperature sensing devices)
- (Current limiting devices)

## 7. (Protection of equipments)

- DC 가 ( , )
- OFF OFF
- ( , )
- 가 가
- , 2 kW

## 7. (Protection of equipments)

### 7.4

(Abnormal temperature protection) :

- (e.g. Short-time heating)

## 7. (Protection of equipments)

### 7.5 (Protection against supply interruption or voltage reduction and subsequent restoration)

- Undervoltage device
- Delayed undervoltage device
- Undervoltage device

## 7. (Protection of equipments)

### 7.6 (Motor overspeed protection)

- 
- 가

### 7.7 (Earth fault/residual current protection)

- 
- 

## 7. (Protection of equipments)

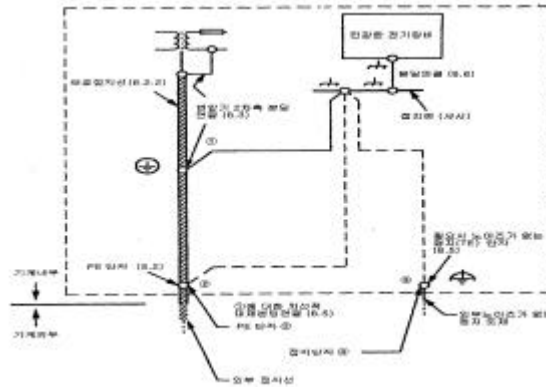
### 7.8 (Phase sequence protection)

- 가

### 7.9 (Protection against overvoltage due to lightning and to switching surges)

- 1
  -
-

8.1 (General): 3



## 8.2 (Protective bonding circuit)

### 8.2.1 (General)

- - PE
- 
- 
-

## 8. (Equipotential bonding)

- 

### 8.2.2 (Protective conductors) :

- GREEN-AND-YELLOW
- Copper conductor ( , ,16 mm<sup>2</sup> )
- 

## 8. (Equipotential bonding)

### 8.2.3 (Continuity of the protective bonding circuit)

- 

- Door Cover

- 

### 8.2.4 (Exclusion of Switching devices from the protective bonding circuit) :

-

## 8. (Equipotential bonding)

### 8.2.5

(Parts which need not be connected to the protective bonding circuit) :

- ( $< 50 \times 50$  mm<sup>2</sup>)
- , 가
- : Screw, Rivets, Nameplates, Contactor/Relay

## 8. (Equipotential bonding)

### 8.2.6

(Interruption of the protective bonding circuit by connectors):

- Plug/Socket
- 가




## 8. (Equipotential bonding)

### 8.2.7

(Protective conductor connecting points)

- 14.1.1

- 가

- 

GREEN-AND-YELLOW

- "PE"

## 8. (Equipotential bonding)

### 8.3

(Bonding for operational purpose)

#### 8.3.1

- :

-

,

-

#### 8.3.2

(Bonding to the protective circuit)

- 2

## 8. (Equipotential bonding)

8.3.3 (Bonding to a common reference potential) :

- 6 ( ) 7 ( )

(Noiseless earth conductor)

- Common mode interferences

PE 가



## 8. (Equipotential bonding)

- (Electrical interference) :

Ground plane) (e.g. Chassis)

- Reference level (Ground plane) :



- Ground plane

## 9. (Control circuits and control functions)

### 9.1 (Control circuits)

#### 9.1.1 (Control circuit supply)

- ( , 가 , 가  
2 , Enclosure  
)

## 9. (Control circuits and control functions)

### 9.1.2 (Control circuit voltage)

- : 250 V
- 

### 9.1.3 (Protection)

-

## 9. (Control circuits and control functions)

### 9.1.4 (Connection of control devices)

- 
- 
- 

### 9.2 (Control functions)

#### 9.2.1 (Start functions)

- 

## 9. (Control circuits and control functions)

### 9.2.2 (Stop functions)

- Category 0:  
(e.g. Uncontrolled stop - )
- Category 1: "0",  
(e.g. controlled stop)
- Category 2 : 가  
Controlled stop
- Category 0 stop

9.

### 9.2.3

- 

### 9.2.4

-

## 9.

### 9.2.5.2 (Start)

- 가
- Interlock
- :
- 
- 
- OFF
- 가

## 9. (Control circuits and control functions)

### 9.2.5.3 (Stop)

- Stop category (0, 1, 2) Risk assessment
- Interlock ( )
- 
- Reset

## 9.

9.2.5.4 ( : Emergency stop,  
emergency switching off)

- EN 418
- 
- 가 -Category 1 stop-)
- (e.g.
- Reset
- Category 0 1 stop
- Category 0 stop “HARDWIRED” :
  - Hardware logic/Software logic - (X)
  - Communications network or link - (X)

## 9. (Control circuits and control functions)

9.2.5.5  
(Monitoring of command actions)

- ,

9.2.5.6 Hold-to-run (Hold-to-run controls)

- Hold-to run

## 9. (Control circuits and control functions)

### 9.2.5.7 (Two-hand control)

(Type 1)

- 가 2
- 가
- 

(Type 2)

- Type 1 가 , 2 OFF

(Type 3)

- Type 2 가 , 2 가 0.5  
가

## 9. (Control circuits and control functions)

### 9.2.6

(Combined start and stop control)

- Push-button 가 2



## 9. (Control circuits and control functions)

### 9.2.7 (Cableless control)

- - 
    - 
    -
  - -
- 가
- 가

## 9. (Control circuits and control functions)

- - 
    -
  - -
  - 
  -
- 가
- 가
- 3
- 가

## 9. (Control circuits and control functions)

### 9.3 (Protective interlocks)

#### 9.3.1

#### (Restoration of interlocked safeguard)

- 

#### 9.3.2 (Overtravel limits)

- Overtravel  
가

## 9. (Control circuits and control functions)

### 9.3.3

#### (Operation of auxillary functions)

-

## 9. (Control circuits and control functions)

### 9.3.4 (Interlocks between different operations and for contrary motions)

- Contactors, Relays,  
Interlock
- Contactor ( )
- Controller가  
Coordination

## 9. (Control circuits and control functions)

### 9.3.5 (Reverse current braking)

- 가 ,

## 9. (Control circuits and control functions)

### 9.4 (Control functions in case of failure)

- 
- :
- (e.g. Interlock-guard, )
- Interlock
- 
- 
- 
- 

## 10. (Operator interface and machine-mounted control devices)

### 10.1.1

- 
- 가
- , , : EN 60073,  
EN 60447

## 10. (Operator interface and machine-mounted control devices)

### 10.1.2 (Location and mounting)

- :
  - , , 가 가
  - 0.6 m
  -

## 10. (Operator interface and machine-mounted control devices)

### 10.1.3 (Protection)

- ( , )
- : EN 60529
- : IP4X

## 10. (Operator interface and machine-mounted control devices)

### 10.1.4 (Position sensors)

- ( , )  
Overtravel
- Interlock  
Normal close

## 10. (Operator interface and **machine**-mounted control devices)

### 10.2 (Push-buttons)

#### 10.2.1 (Colors)

- START/ON ----- **WHITE**, GRAY, BLACK
- STOP/OFF ----- **BLACK**, GRAY, WHITE
- SAFE/NORMAL --- GREEN
- ABNORMAL ----- YELLOW
- EMERGENCY STOP ---- RED

## 10.

### 10.2.2 (Markings)

- START or ON :



- STOP or OFF :



- START / STOP or ON / OFF :



- Hold-to-Run :



## 10.

### (Operator interface and machine-mounted control devices)

### 10.3 (Indicator lights and displays)

- RED ----- EMERGENCY

- YELLOW ----- ABNORMAL

- GREEN ----- NORMAL

- BLUE ----- MANDATORY

- WHITE ----- NEUTRAL

## 10. (Operator interface and machine-mounted control devices)

### 10.4 (Illuminated push-buttons)

- 2 3
- White
- Red Emergency

### 10.5 (Rotary control devices)

- 가 ( , )

## 10.

### 10.7 (Devices for emergency stop)

#### 10.7.1 (Location)

- 
- Panel

#### 10.7.2 (Types)

- Normal close Self-latch type
  - Push-button (Mushroom head)
  - Pull-cord
  - Pedal-operated (가 )



## 10.

### 10.7.3

- Reset
- 가 ,
- Reset

### 10.7.4 (Actuators)

- Red ,
- Panel Yellow

## 10.

## (Operator interface and machine-mounted control devices)

### 10.7.5

- ,
- 가
- 10.7.4 가

## 10. (Operator interface and machine-mounted control devices)

### 10.8 (Devices for emergency switching off)

#### 10.8.1 (Location)

- 가 Panel
  - ,
- Category 0

## 10. (Operator interface and machine-mounted control devices)

### 10.8.2 (Types)

- Normal close
  - Push-button (Mushroom head)
  - Pull-cord
- Push-button

## 10.

### 10.8.3

- Reset

- 가

,

Reset

### 10.8.4 (Actuators)

- Panel Yellow Red ,

Panel Yellow

Red

## 10.

## (Operator interface and machine-mounted control devices)

### 10.8.5

- ,

- 가

- 10.8.4 가

## 10. (Operator interface and machine-mounted control devices)

### 10.9 (Displays)

- - 가 , Flashing type  
Rotary type , 가
- 

## 11. (Electronic equipment)

### 11.1

- (PLC) ,  
PCB

### 11.2

#### 11.2.1 (Inputs and outputs)

- 
-

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## 11. (Electronic equipment)

### 11.2.2 (Equipotential bonding)

- , / Rack 8
- 가

### 11.3 (Programmable equipment)

#### 11.3.1 (Programmable controllers)

- EN 61131-1 EN 61131-2

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## 11. (Electronic equipment)

### 11.3.2 (Memory retention and protection)

- Memory
- Programmable controllers Category 0  
가

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## 12. : (Controlgear: location, mounting, and enclosures)

### 12.1

- 

- 가
- 

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## 12. : (Controlgear: location, mounting, and enclosures)

### 12.2 (Location and mounting)

- 

가

- : 0.4 m ~ 2.0 m

(Terminal: 0.2 m )

- Plug-in

- 

Enclosure

-

12. :  
(Controlgear: location, mounting, and enclosures)

12.3 (Degrees of protection)

- - IP22
  - Enclosure: IP54
    - Controlgear enclosure: IP54
    - Ventilated enclosure ( ): IP22
    - Motors: IP23
    - Ventilated enclosure ( ): IP33
    - Controlgear: IP66

12. :  
(Controlgear: location, mounting, and enclosures)

12.4 (Enclosures, doors and openings)

- : 3 mm
- 0.9 m 95 °

## 13. (Conductors and Cables)

### 13.1

- 가 , , ,
- 

### 13.2 (Conductors)

- (Copper)
- : 4

## 13. (Conductors and Cables)

### 13.3 (Insulation)

- PVC, RUBBER, SIR, XLPE
- :
- > 50 Vac or 120 Vdc  $\Rightarrow$  2000 Vac/5
- $\approx$  PELV  $\Rightarrow$  500 Vac/5

### 13.4 (Current carrying capacity in normal service)

- 4



## 13. (Conductors and Cables)

### 13.4 (Conductor and cable voltage drop)

- 5%
- 5

### 13.5 (Minimum cross-sectional area)

- 6

## 13. (Conductors and Cables)

### 13.7 가 (Flexible cables)

- Class 5 Class 6 (가 )

-

- 가

-

15 N/mm<sup>2</sup>)

- 

7

## 13. (Conductors and Cables)

13.8 (Collector wires, collector bars, slip-ring assemblies)

- IP2X IP4X
- 가 가 Pull-cord
- PE N  
가
- (Creepage distance):
  - : 60 mm
  - : 30 mm

## 14. (Wiring practices)

14.1 (Connections and routing)

- ( , )
- /
- (splice)
- 가
- Loop impedance
- 가
-

## 14. (Wiring practices)

### 14.2 (Identification of conductors)

- Green Yellow GREEN-AND-YELLOW  
가
- Light blue
- , ,
- ,
- 
- Black : AC DC
- Red : AC
- Blue : DC
- Orange: Interlock

## 14. (Wiring practices)

### 14.3 Enclosure

- Panel conductor
- Channel Duct (IEC 60332-1)
- Enclosure 가

### 14.4 Enclosure

- Cable Duct / Enclosure IP
- Plug/Socket Plug

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## 14. (Wiring practices)

### 14.5 Ducts, Connection Junction Box

- Duct Junction box
- Duct IP : IP33
- 6 mm Drain hole
- Oil/Air/Water pipe
- Duct Cable tray 2 m
- Enclosure

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## 15. (Electric motors and associated equipment)

- EN 60034-1
- , , (DC ),
- IP 23
- IEC 60072-1, 72-2
- Nameplate
-

## 16.

### 16.1 (Accessories)

- Socket outlet EN 60309-1
- Socket outlet 가 250 Vac, 16 A
- Socket outlet 가
- Socket outlet /
- Socket

## 16.

### 16.2 (Local lighting)

- 8.2.2
- 가
- 
- 250 V
-

## 17. (Marking, warning signs)

### 17.1 (Nameplates)

- , ,
- 

### 17.2 (Warning signs)

- Enclosure Symbol  
(60417-2-EN-5036)



## 17. (Marking, warning signs)

### 17.3 (Functional Identification)

- Man-Machine Interface  
EN 60417, ISO 7000 ' Symbol

### 17.4 (Marking of control equipment)

- ,
- 
- 
- , ,

## 17. (Marking, warning signs)

### 17.5 (Reference designations)

- 
- , 가

## 18. (Technical documentation)

### 18.1

- , ,
- 

### 18.2

- a) , ,
- b) ( , , )
- c) ( , , , )
- d) (System Block Diagram)
- e) (Circuit Diagram)

## 18. (Technical documentation)

f)

1)

2)

3)

4)

5)

,

,

6) Parts list ( , Spare parts list)

g) Safeguards, , Interlock

h) Safeguards

## 18. (Technical documentation)

18.3

- EN 61082-1

- Symbol IEC 60750

- 가 가

18.4

- ( )

- , ,

- 

- , Peak ,



## 18. (Technical documentation)

### 18.5

- ,
- ,
- Duct ,

### 18.6 ( ) (System Diagram)

- 
- (Function Diagram)

## 18. (Technical documentation)

### 18.7 (Circuit Diagram)

- EN 60617 Graphic symbol  
Symbol (Legends)
- 
- 

### 18.8 (Operating Manual)

- ,
- 
-

## 18. (Technical documentation)

### 18.9 (Maintenance Manual)

- , , ,
- 

### 18.10 (Parts List)

- Spare parts list
- 가
- , Spec., ,

## 19. (Testing and verification)

### 19.1

- 
- 
- .
- 
- (19.2)
- (19.3)
- (19.4)
- (19.5)
- (19.6)

## 19. (Testing and verification)

### 19.2 (Continuity of protective bonding circuit)

- : PELV , 10 A, 50 Hz/60 Hz
- 가 : PE
- : 9

### 19.3 (Insulation resistance tests)

- : 500 Vac
- 가 :
- : 1 Mohm

## 19. (Testing and verification)

### 19.4 (Voltage tests)

- : 1000 V ( x 2)
- 가 : , 1
- : 가
- 가 가

## 19. (Testing and verification)

### 19.5 (Protection against residual voltages)

- 60 V 가  
5 60 V 가  
• Plug pin 1

### 19.6 (Functional tests)

- Safeguarding
-


**CE**

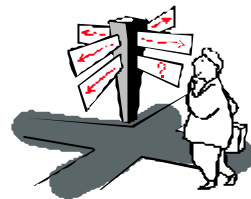
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**( )**



• :

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Email : ickim@onetech.co.kr  
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- :
  - FDA 510(k)
  - UL (Safety)
  - FCC Part 15 or Part 18 (EMI)
- - CE Marking
  - AIMD
  - MDD
  - IVDD
  - LVD/EMCD



## \_FDA 510(k) (I)

- :  
 DHHS( ) PHS( ) , FDA( );  
 CDRH( )  
 (FDA , , , , .)  
 ( Kxxxxxx .)  
 Home page : [www.fda.gov/cdrh](http://www.fda.gov/cdrh)
- :  
 - Class I, Class II : General Control  
 - Class I , Class II, Class III :  
   510(k) 가 (Premarket Notification);  
   General Control + 510(k) Submission  
 - Class III, New Device : (Premarket Approval)



## \_FDA 510(k) (II)

- (General Control):
  - Establishment Registration) : 30  
 FDA .
  - Device Listing: 30 FDA .
  - (QSR, Quality System Regulation) :  
☒ GMP ISO9001 + ISO13485 .  
☒ Class III , 2 1 .
  - (Labeling Regulation) :  
☒ / (ID Label) / (Instructions for Use) /  
 (brochure, home page ),  
☒ / /
  - (MDR, Medical Device Reporting):



## \_FDA 510(k)(III)

### • 510(k) Submission

#### □ \_\_\_\_\_:

-> Consultant -> (Third Party ->) FDA CDRH

- \* FDA : 90 , Third Party 30
- \* Third Party : TUV PS, UL ( 가 / )

#### □ Hot Issue:

- ✓ Predicate Device : FDA 가 , /
- ✓ Intended Use :
- ✓ Software : 가 , /



## \_FDA 510(k) (IV)

### □ 510(k) Submission:

vs

	Premarket Notification 510(k): Regulatory Requirements for Medical Devices
(Labeling)	Device Labeling Guidance - , , , (ID Label), (packaging)
Software Validation	Guidances for the Content of Premarket Submissions for Software Contained in Medical Devices - IEC 60601-1-4 . (Risk Analysis )
(Biocompatibility)	In Vitro Diagnostic Devices: Guidances for the Preparation of 510(k) Submission - ISO 10993-1 .
(Sterility)	Premarket Notification 510(k): Regulatory Requirements for Medical Devices
	가 ) - NIBP Guidance
(Performance Standard)	(ANSI/AAMI , ASTM ) - ANSI/AAMI SP10, - ANSI/AAMI EC11, - ANSI/AAMI ST55
(Voluntary Standard)	(Safety) - IEC 60601-1, IEC61010-1 ; (EMC) - IEC60601-1-2 / (test report) .





## FDA 510(k) (V)

- Experiences in ONETECH:

- (1) Blood pressure meter (monitor) : NIBP, Class II, Third Party
- (2) TENS : Class II, Third Party
- (3) Incontinence Equipment : Class II, Third Party
- (4) Insulin Syringe : Class II, Third Party
- (5) Ultrasound Scanner : Class II, Third Party
- (6) Table-Top Steam Sterilizer : Class II, Third Party (pending)
- (7) Infrared Ear Thermometer : Class II, Third Party (pending)
- (8) Body Composition Analyzer : Class II (pending)
- (9) Patient Monitor : Class II (pending)



## UL

- UL – Safety Approval:

- (1)
  - UL2601-1 + IEC 60601-2-xx
  - In Vitro , - UL3101-1 + IEC 61010-2-xx
- (2) UL .
- (3) (Witness Testing) : UL Engineer
- (4) : Witness 2-3



## \_FCC

- FCC( ) – EMI Verification:

(1)

FCC Part 15, Digital Device

FCC Part 18, ISM with intended RF Energy emission

(2)

(3) Verification:

(4) Part 18 : , MRI



## \_CE Marking(I)

- \_\_\_\_\_

- ✓ AIMD (Active Implantable Medical Device Directive)
- ✓ MDD (Medical Device Directive)
- ✓ IVDD (In-Vitro Diagnostic Device Directive)
- ✓ LVD (Low Voltage Directive)
- ✓ EMC Directive (Electromagnetic Compatibility Directive)



## \_CE Marking (II)

- AIMD / MDD / IVDD

- ✓ Technical File
- ✓ Quality Assurance
- ✓ Product Evaluation
- ✓ IVDD: 2000.6.7 ; 2003.12.7  
( )

- LVD / EMCD

- ✓ Product Evaluation
- ✓ (EN60601-1) 가 ( : Power Supply, Monitor, Printer )
- ✓ (Veterinary Use)
- ✓ IVDD (IVDD )



## \_CE Marking(III)

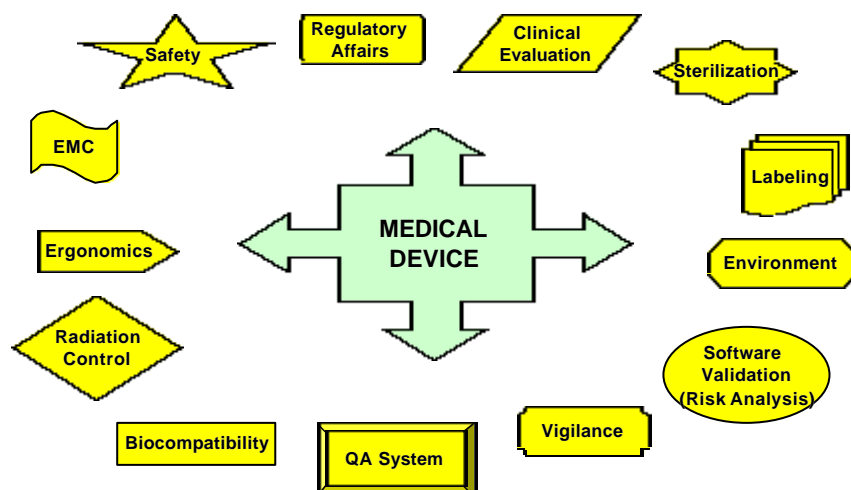
- \_\_\_\_\_
- ✓ AIMD (Active Implantable Medical Device Directive)
- ✓ MDD (Medical Device Directive)
- ✓ IVDD (In-Vitro Diagnostic Device Directive)
- ✓ LVD (Low Voltage Directive)
- ✓ EMCD (Electromagnetic Compatibility Directive)



# CE Marking

## Medical Device Directive -93/42/EEC

ONETECH Corp.





## CE Marking Major Issues

- ◆ Technical File
- ◆ Risk Analysis/Software Validation
- ◆ Clinical Evaluation
- ◆ Product/Material Test Report
- ◆ Quality Assurance
- ◆ Authorized Representative
- ◆ Declaration of Conformity
- ◆ MDD Audit / Notified Body



## (Classification)

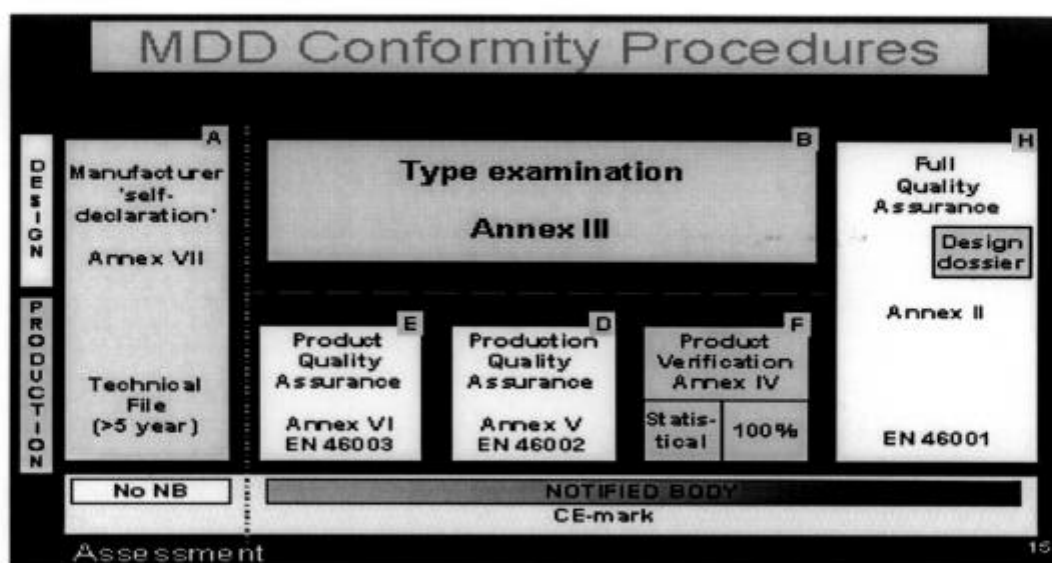
- ∞ Class I
- ∞ Class II a
- ∞ Class II b
- ∞ Class III

# 분류 예: X-ray Equipment

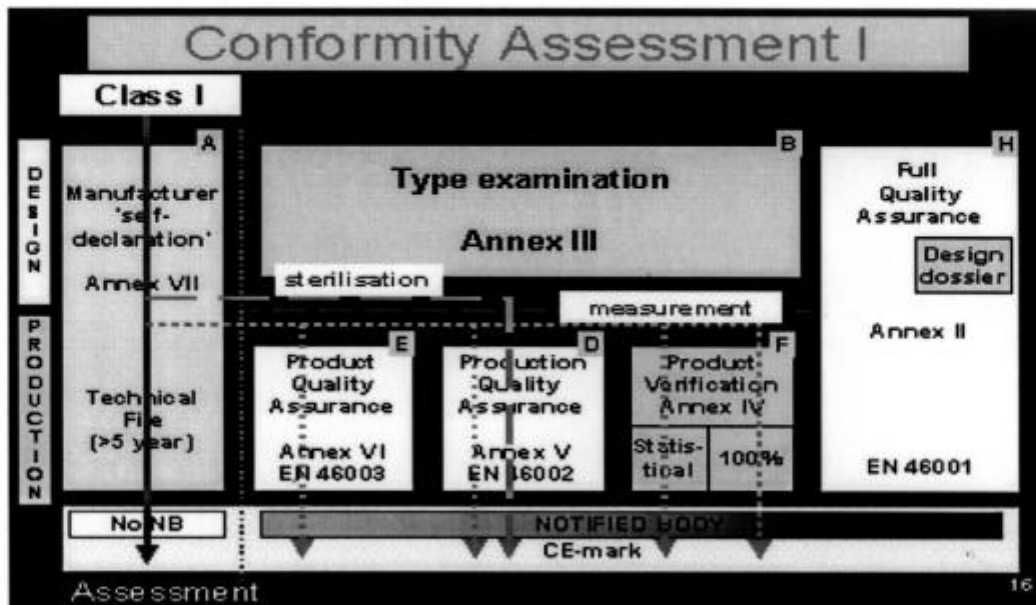
MDD, Annex IX, Rule 10  
Active device, Ionizing radiation,  
Radiology;

**Class IIb**

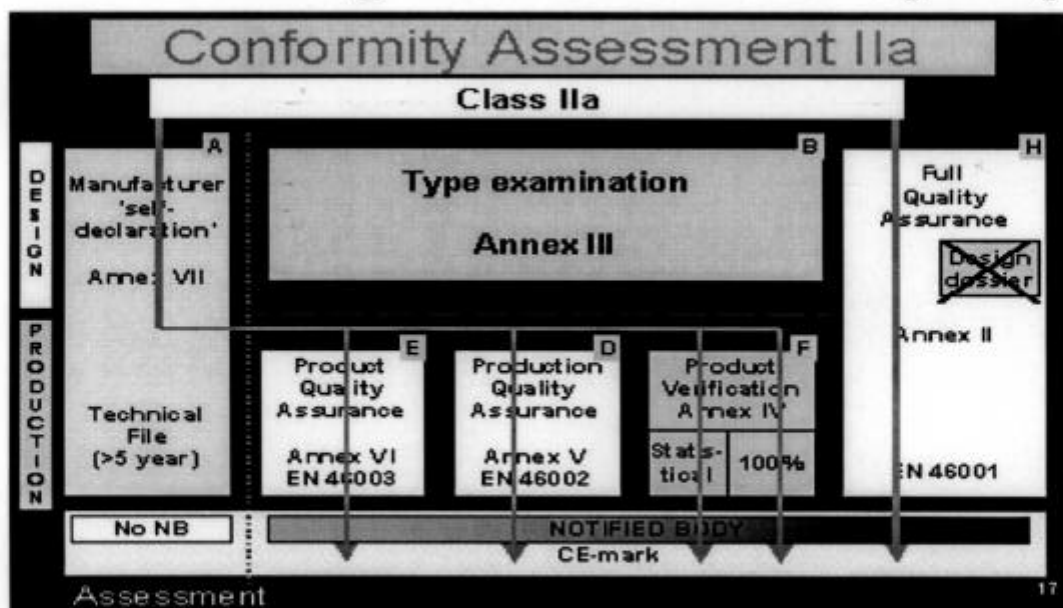
## CE Marking 적합성 평가절차



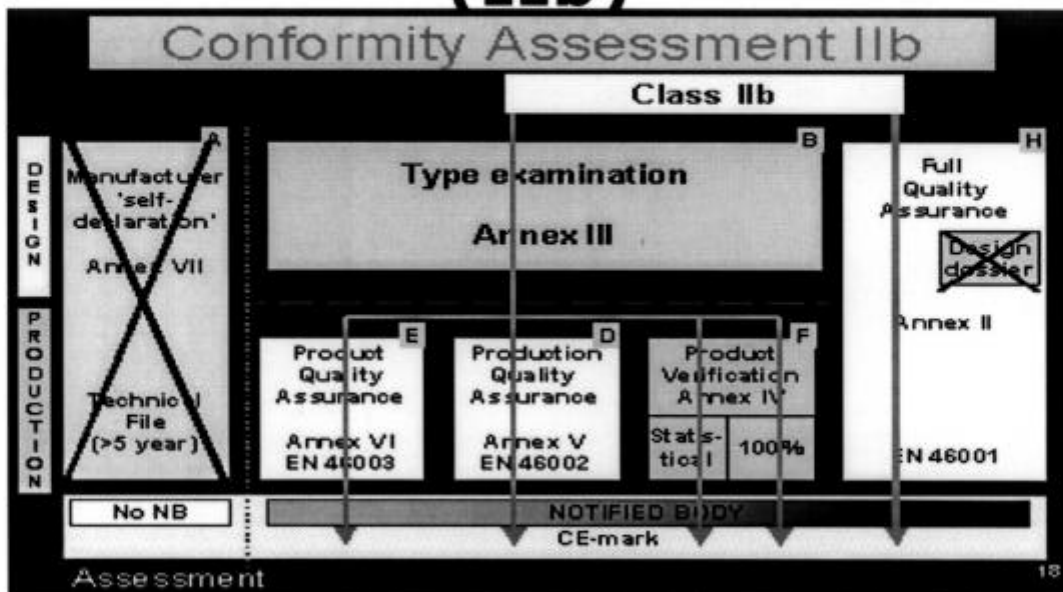
# CE Marking 적합성 평가절차(I)



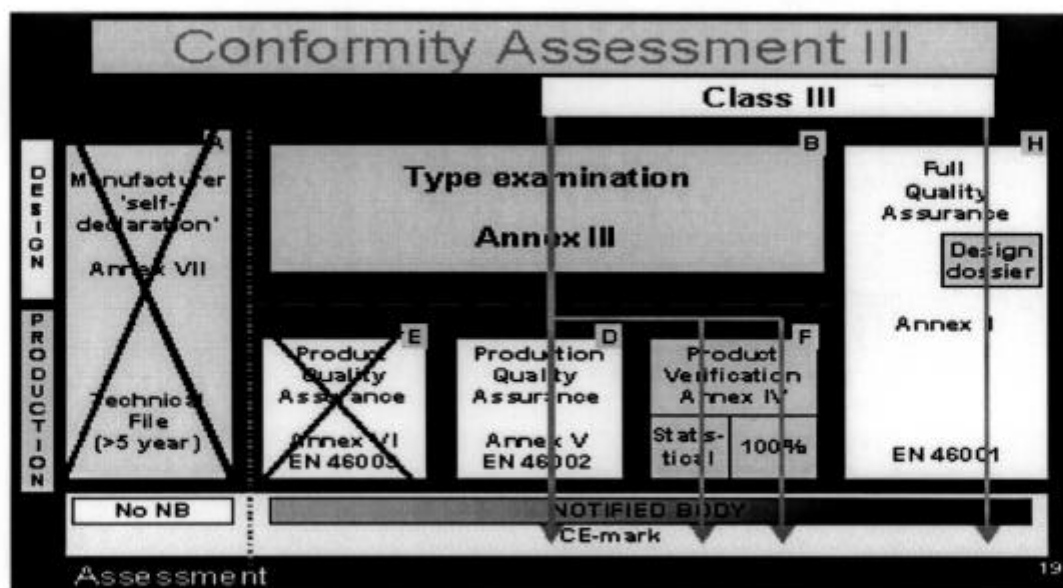
# CE Marking 적합성 평가절차(IIa)



# CE Marking 적합성 평가절차 (I Ib)



# CE Marking 적합성 평가절차(III)





## Harmonized Standards



- Safety of medical devices(EN60601 - 1)
- EMC of medical devices(EN60601 - 1 - 2)
- X-ray Radiation (EN60601 - 1 - 3)
- Programmable devices(EN60601 - 1 - 4)
- Quality system for medical devices  
(ISO 9000 Series & EN 46000 Series)
- Sterilization of medical devices(EN 550/552/554)
- Biological testing of medical devices(EN 30993-x)
- Risk Analysis(EN 1441)
- Clinical investigation(EN 540)
- Labeling(EN 1041)
- Symbols(EN 980)

## Safety Test



- EN60601 - 1(+A1+A2), Safety of Medical Electrical Equipment, Part 1: General Requirements
- EN60601 - 1 - 1(+A1), Medical Electrical Systems
- EN60601 - 2 - xx, Safety of Medical Electrical Equipment, Part 2: Particular Requirements



## EMC Test

- ◆ Standard: EN60601-1-2
- EMI: RE+CE, Group 1, Class A
- EMS
  - RS, EFT/Burst, Surge, ESD

## (Technical File)



1. <u>Document Maintenance Policy</u> , , ,	8. <u>Result of Risk Analysis</u>
2. <u>Intended Purpose</u>	9. <u>Instructions for Use</u>
3. <u>Classification and Assessment Route</u> 가	10. <u>Labeling</u> (ID Label), ,
4. <u>Quality Assurance</u> , ,	11. <u>Clinical Evaluation Data</u> 가
5. <u>Product Description</u> , ( , , catalog) (Variants) , (life)	12. <u>Vigilance and Post Market Policy</u> Recall 13. <u>Appointment of Authorized Representative</u> 12
6. <u>List of Standards applied in Full or Part</u> 가	14. <u>Declaration of Conformity</u> 15. <u>Notified Body intervention</u> (NB) / ,
7. <u>Essential Requirement checklist</u>	15. <u>Registration with Competent Authority</u> (1 )



## 가(Clinical Evaluation)

- ◆ (anatomic area)  
(intended Use) 가
- ◆ Scientific Route
  - \_\_\_\_\_
  - \_\_\_\_\_
  - \_\_\_\_\_
- Clinical Trial Route
  - \_\_\_\_\_
  - \_\_\_\_\_ 가 \_\_\_\_\_
  - \_\_\_\_\_

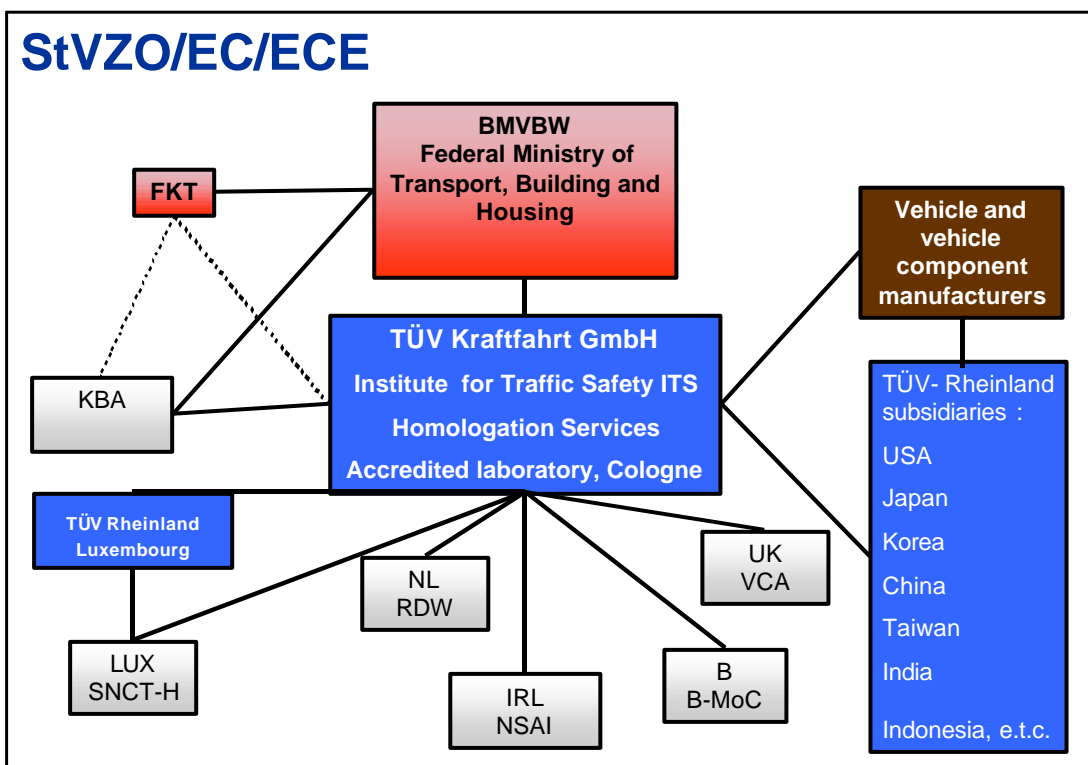
**CE** : ,

TUV Rheinland Korea Ltd.



## CONTENT:

1. The European Union approval system of vehicles and vehicle components and parts  
- **EC- Approval System** -
2. The UN- ECE- system with approvals according to the ECE- Regulations  
- **ECE- Regulation System** -
3. The global harmonization of existing standards  
- **Global Agreement** -



## - EC- Approval System - Background

- **Post-war Europe & Economic Development**

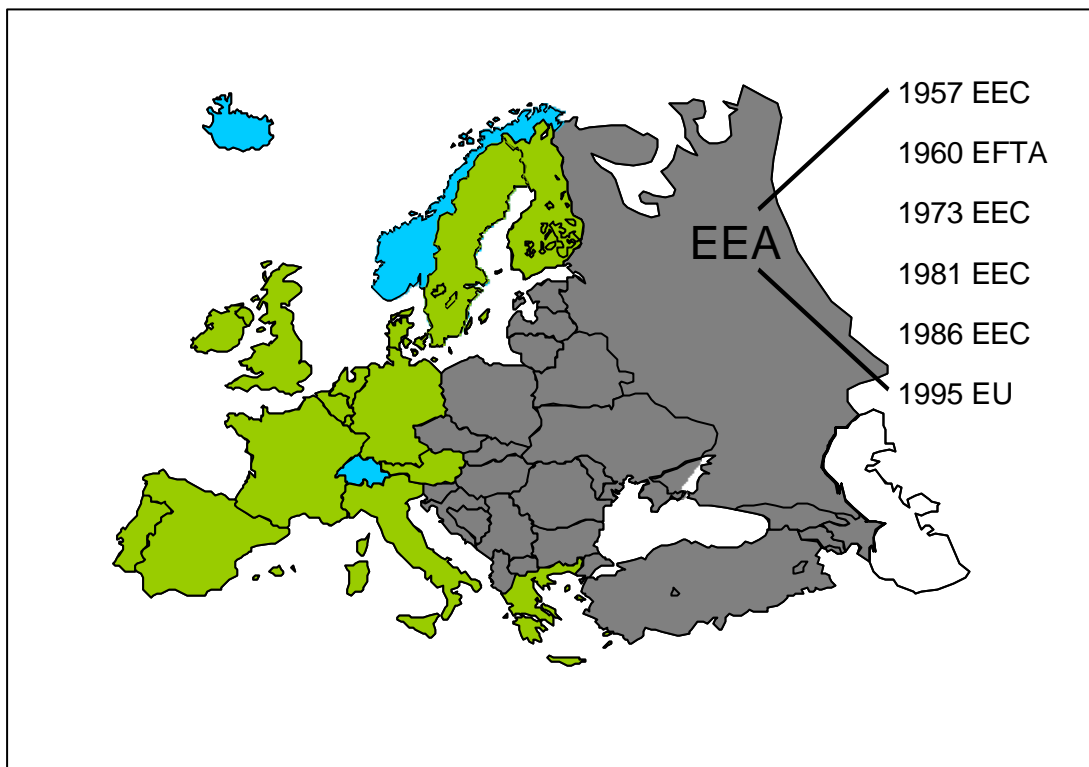
- mobility
- mass production & mass traffic
- need for safety rules & technical standards
- national tasks
- economic situation & importance of automotive business
- trade barriers



## - EC- Approval System - Background

- **Political Processes of Harmonization in Europe**

- EC / EU (Treaty of Rome 1957)
  - *realization of internal market with free movement of goods, persons, services and capital*
- UN / ECE (Geneva Agreement 1958)
  - *global trust & stability, harmonized technical standards*
- EFTA European Free Trade Association (Stockholm 1959)
  - **members** : **Switzerland, Norway, Iceland, Liechtenstein**
  - **ex-members** : **Sweden, Finland, Austria (now EU)**



## - EC- Approval System -

Member states of the European Union			
Country	EC Symbol	Country	EC Symbol
Germany	e 1	Austria	e 12
France	e 2	Luxembourg	e 13
Italy	e 3	Finland	e 17
The Netherlands	e 4	Denmark	e 18
Sweden	e 5	Portugal	e 21
Belgium	e 6	Greece	e 23
Spain	e 9	Ireland	e 24
United Kingdom	e 11		



## - EC- Approval System -

### Background



- Treaty of Rome 1957
- political and economic targets
  - start as a community to harmonize trade with steel and coal
  - common nuclear power control standards
  - extend common market ideas to other industries (fishery, forestry, agriculture...)
  - stop trade barriers in general
  - improve public and social standards
  - start a system of common directives to be accepted EEC-wide

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## - EC- Approval System -

### Background (cont.)

- political ideas
  - central EU institutions propose directives for harmonization
  - commission addresses member states to adopt directives
  - obligation to implement directives
  - acceptance of a common time frame fixed in directives

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## - EC- Approval System -

### Background (cont.)

- automotive business
  - high importance in the major member states (D, F, I, GB, E)
  - impact on road safety  
(example Germany:
    - 80 million inhabitants
    - 51 million registered vehicles (incl. trucks)
    - 1 of 7 jobs in automotive and related business)

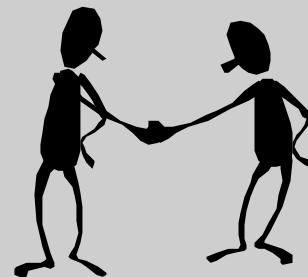


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## - EC- Approval System -

### Background (cont.)

- legislation for traffic safety
  - idea of integral requirements
    - *whole vehicle type approval (WVTA)*
    - *common approval processes*



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## - EC- Approval System -

### Background (cont.)

- All European countries have vehicle safety regulations
- All European countries have their own approval process
- Variation of detailed requirements are enormously
- Bad compatibility due to different & strange technical details
- Misuse to protect home market & own industry
- Improvement by adoption of European Regulations and Directives
- Lack of European provision ‚filled‘ by national requirements



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## - EC- Approval System -

### The 4 targets to realize the European market until 1992:

1. Free movement of all persons within the European member states
2. Free trade within the European member states
3. Harmonization of all services ( Transport/  
Telecommunication e.t.c.)
4. Free capital market



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## - EC- Approval System -

Two parallel systems for the certification of motor vehicles and their components:

- **EC** (European Community = predecessor of the European Union) **DIRECTIVES**
- **ECE** (Economic Commission for Europe) **REGULATIONS**



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## - EC- Approval System -

### The EC- Directives

- EC Directives are required by the European Union (EU)
- The European Council issues these directives and all member states must accept products approved in one of the member states according to European law
- All EC Directives are published in the official languages of the European communities (11 languages)
- Commission proposals are also published in the Official Journal (OJ) of the EC
- This system allows interested parties to have an input into the process at varying levels

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## - EC- Approval System -

- „General Programme for the Elimination of Technical Barriers to Trade“ of 1969 incorporated the procedure for type-approval of motor vehicles and their trailers
- In February 1970, the first Directive adopted in accordance with this Programme was Directive 70/156/EEC:  
    „Approximation of the laws of the Member States relating to the  
    Type Approval of motor vehicles and their trailers“,  
    the so-called „framework Directive“

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## - EC- Approval System -

### Other framework directives:

- 70 / 156 / EEC, vehicles and their trailers
- 74 / 150 / EEC, tractors
- 92 / 61 / EEC, 2 & 3- wheeled vehicles

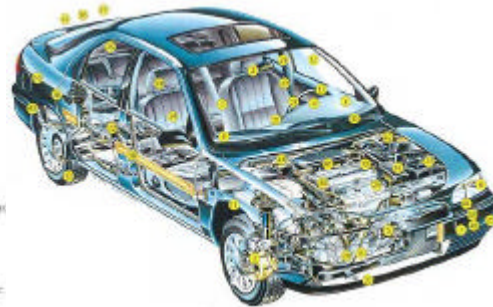


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## - EC- Approval System -

### Homologation

European Whole Vehicle Type approval  
to directive 70 / 156 / EEC including  
98 / 14 / EC and ECE - Regulations



1. Available energy  
93/259/EEC - 93/259/EEC  
ECE R100
2. Noise levels  
71/317/EEC - 88/241/EEC  
ECE R59 - ECE R59.01
3. Emissions  
71/303/EEC - 88/122/EEC  
ECE R69 - ECE R69.01
4. Suspension and steering gear  
75/704/EEC - 87/320/EEC  
ECE R55
5. Brakes (discs)  
76/114/EEC - 87/240/EEC  
ECE R90
6. Lighting installations  
76/762/EEC - 87/240/EEC  
ECE R68 - ECE R68.01
7. Speedometer and odometer  
77/662/EEC - 94/25/EEC  
ECE R39 - ECE R39.01
8. Vehicle category of construction  
78/130/EEC - 94/25/EEC  
ECE R39 - ECE R39.01
9. Different features  
78/130/EEC  
ECE R39
10. Vehicle category  
78/130/EEC - 94/25/EEC  
ECE R39
11. Safety seats  
78/130/EEC - 94/25/EEC  
ECE R44
12. Tyres  
92/25/EEC  
ECE R40 - ECE R40.01
13. Speed limits  
92/25/EEC - 94/25/EEC  
ECE R44 - ECE R44.01
14. Emissions  
79/240/EEC - 92/25/EEC  
ECE R69 - ECE R69.01
15. Fuel tanks & oil / gas resistance devices  
90/269/EEC - 97/18/EEC  
ECE R69 - ECE R69.01
16. Noise  
90/241/EEC - 92/25/EEC  
ECE R59 - ECE R59.01
17. Door locks and hinges  
90/269/EEC  
ECE R11 - ECE R11.01
18. Suspension (front)  
92/269/EEC - 93/25/EEC  
ECE R10 - ECE R10.01
19. Brakes (discs)  
92/269/EEC - 93/25/EEC  
ECE R90 - ECE R90.01
20. Brakes (discs) and steering gear  
92/269/EEC - 93/25/EEC  
ECE R90 - ECE R90.01
21. Bushings  
92/269/EEC - 93/25/EEC  
ECE R11 - ECE R11.01
22. Protective covering  
92/269/EEC - 93/25/EEC  
ECE R11 - ECE R11.01
23. Fuel tanks  
92/269/EEC - 93/25/EEC  
ECE R69 - ECE R69.01
24. Emissions  
92/269/EEC - 93/25/EEC  
ECE R69 - ECE R69.01
25. Fuel tanks & oil / gas resistance devices  
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68. Fuel tanks & oil / gas resistance devices  
92/269/EEC - 93/25/EEC  
ECE R69 - ECE R69.01
69. Fuel tanks & oil / gas resistance devices  
92/269/EEC - 93/25/EEC  
ECE R69 - ECE R69.01
70. Fuel tanks & oil / gas resistance devices  
92/269/EEC - 93/25/EEC  
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ECE R69 - ECE R69.01
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ECE R69 - ECE R69.01
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ECE R69 - ECE R69.01
76. Fuel tanks & oil / gas resistance devices  
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77. Fuel tanks & oil / gas resistance devices  
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ECE R69 - ECE R69.01
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80. Fuel tanks & oil / gas resistance devices  
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ECE R69 - ECE R69.01
81. Fuel tanks & oil / gas resistance devices  
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ECE R69 - ECE R69.01
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ECE R69 - ECE R69.01
99. Fuel tanks & oil / gas resistance devices  
92/269/EEC - 93/25/EEC  
ECE R69 - ECE R69.01
100. Fuel tanks & oil / gas resistance devices  
92/269/EEC - 93/25/EEC  
ECE R69 - ECE R69.01

## - EC- Approval System -

Directive 70 / 156 / EEC

Directive 92 / 61 / EEC

- The European Whole Vehicle Type Approval (WVTA) replacing the individual national type approvals of the EU Member States is an efficient, economic and convenient system
- The European WVTA is mandatory
  - for passenger cars from January 1, 1998
  - for motor cycles from June 17, 1999



## - EC- Approval System -

### Directive 70 / 156 / EEC (cont.)

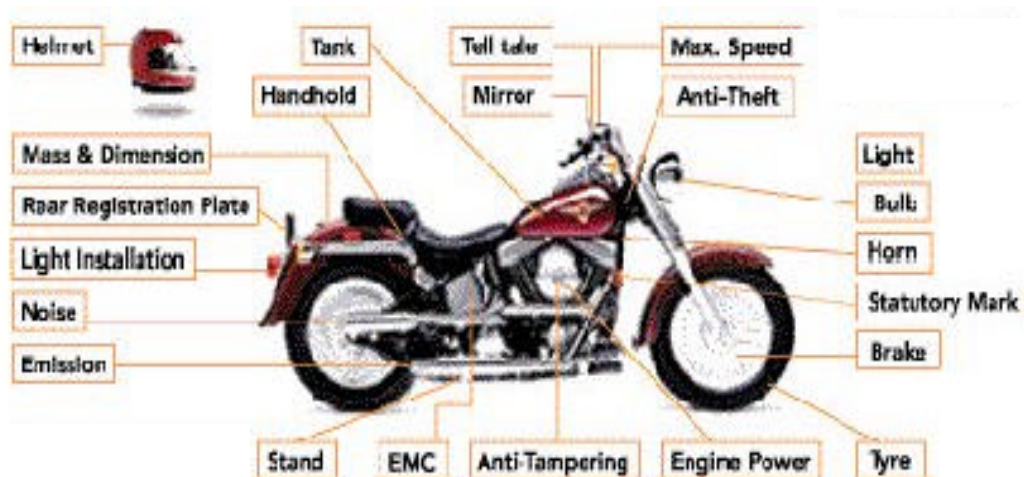
- fixed implementation schedule for passenger vehicles
  - 01.01.1993: optional start of WVTa parallel to NTA
  - 01.01.1996: mandatory system for new vehicle types
  - 01.01.1998: cancellation of all NTA for passenger vehicles
- awaiting schedule for other vehicles in the next years



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## - EC- Approval System -

### - Directive 92 / 61 / EEC

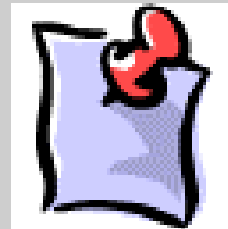


22

## - EC- Approval System -

### Vehicle type approval directives

- 70 / 156 / EEC
  - vehicles and their trailers
- 74 / 150 / EEC
  - tractors
- 92 / 61 / EEC
  - 2- & 3- wheeled vehicles



### notes:

- numbering system of directives:
  - year of issue / number of directive in that year / suffix
- meaning of suffix:
  - EEC= European Economic Community
  - EC = European Community (since 1994)

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## - EC- Approval System -

- Type approval is the procedure whereby a manufacturer can obtain certification from 'a competent authority' that his product meets the requirements of one or more than one **EC Directive**
- The Whole Vehicle Type Approval (WVTA) is the procedure whereby a manufacturer can obtain certification from 'a competent authority' that the vehicle meets the requirements of the so-called *framework Directive (70/156/EEC)*

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## - EC- Approval System -

### Directive 70 / 156 / EEC

- published 1970 to harmonize vehicle type approval
- frame directive to include detailed technical requirements
- reference to separate directives
  - requirements for systems, components, separate technical units
- process to set up detailed requirements for passenger cars
  - 22 years period 1970 - 1992
  - finalisation of vehicle type approval procedure with amendment directive 92 / 53 / EEC
  - still ongoing process to adapt technical progress

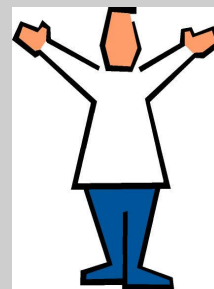
25

## - EC- Approval System -

### 70/156/EEC - the framework Directive

#### Content

- Scope of Application
- Definitions
- Application for type approval
- Type approval process
- Amendments to approvals
- Certificate of conformity
- Registration and entry into service
- Exemption and alternative procedures
- Acceptance of equivalent approvals
- Conformity of production arrangements
- Nonconformity with the approved type
- Notification of approval authorities and technical services



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## - EC- Approval System -

### Directive 70/156/EEC Definitions

- **Scope**

- motor vehicles and their trailers
- systems, components and separate technical units for use on such vehicles and trailers



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## - EC- Approval System -

### Directive 70/156/EEC Definitions

- **Technical requirements**

- list of separate directives (Annex IV Part I)
- applicable equivalent regulations (Annex IV Part II)

- **Conformity of production procedures**

(see separate part of presentation)



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## - EC- Approval System -

### Directive 70/156/EEC Definitions



- **Vehicle categories**
  - M (M1, M2, M3), transport of passengers
  - N (N1, N2, N3), transport of goods
  - O (O1, O2, O3, O4), trailers
  - ... G (off-road vehicles in category M or N)
- **Note: Other vehicle categories**
  - tractors: no codes existing
  - vehicles with less than 4 wheels: L (L1, L2, L3, L4, L5)

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## - EC- Approval System -

### Vehicle categories

**M** passenger vehicles

**M1** ≤ 9 seats

**M2** > 9 seats, ≤ 5000 kg

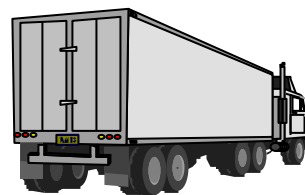
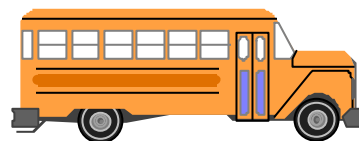
**M3** > 9 seats, > 5000 kg

**N** commercial vehicles

**N1** ≤ 3500 kg

**N2** > 3500 kg, ≤ 12000 kg

**N3** > 12000 kg



30

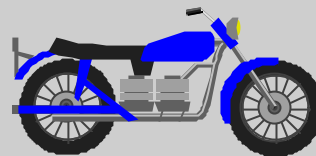
## - EC- Approval System -

### Vehicle categories (cont.)

- O trailers (incl. semi-trailers)
- O1 ≤ 750 kg
- O2 > 750 kg, ≤ 3500 kg
- O3 > 3500 kg, ≤ 10000 kg
- O4 > 10000 kg



- L vehicles with less than four wheels
- L1 2 wheels, ≤ 50 cc, ≤ 45 km/h
- L2 3 wheels, ≤ 50 cc, ≤ 45 km/h
- L3 2 wheels, > 50 cc or > 45 km/h
- L4 3 wheels, > 50 cc or > 45 km/h
- L5 3 wheels, symmetrical to vehicle center-line, ≤ 1000 kg, > 50 cc or > 45 km/h



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## - EC- Approval System -

### Directive 70/156/EEC - Definitions

- **Vehicle:** any motor vehicle intended for use on the road, being complete or incomplete, having at least four wheels and a maximum design speed exceeding 25 km/h, and its trailers, with the exception of vehicles which run on rails and of agricultural and forestry tractors and all mobile machinery
- **Multi-stage type approval:** the procedure whereby one or more Member States certify that, depending on the state of completion, an incomplete or complete vehicle type satisfies the relevant technical requirements of the Directive/s

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## - EC- Approval System -

### Directive 70/156/EEC - The definition of different approvals

- **System:** any vehicle system such as brakes, emission control equipment, interior fittings, etc. which is subject to the requirements in any of the separate Directives
- **Component:** a device, such as a lamp, subject to the requirements of a separate Directive, intended to be part of a vehicle, which may be type-approved independently of a vehicle where the separate Directive makes express provisions for so doing
- **Separate technical unit** a device, such as a rear protective device, subject to the requirements of a separate Directive, intended to be part of vehicle, which may be type-approved separately but only in relation to one or more specified types of vehicle, where the separate Directive makes express provisions for so doing

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## - EC- Approval System -

### 'Component' approval according to EC (examples)

- |                  |                                 |
|------------------|---------------------------------|
| • mirror         | 71 / 127 / EEC                  |
| • seat           | 74 / 408 / EEC (96 / 37 / EC)   |
| • rear reflector | 76 / 757 / EEC (97 / 29 / EC)   |
| • head lamp      | 76 / 761 / EEC (1999 / 17 / EC) |
| • seat belt      | 77 / 541 / EEC                  |
| • head rest      | 78 / 932 / EEC                  |
| • speedometer    | 2000 / 7 / EC                   |



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## - EC- Approval System -

### 'Separate technical unit' approval according to EC (examples)

- |                               |                |                |
|-------------------------------|----------------|----------------|
| • replacement muffler         | 70 / 157 / EEC |                |
| • rear underrun protection    | 70 / 221 / EEC |                |
| • replacement brake lining    | 71 / 320 / EEC | (98 / 12 / EC) |
| • EMC: electronic subassembly | 72 / 245 / EEC | (95 / 54 / EC) |
| • immobilizer                 | 74 / 61 / EEC  | (95 / 56 / EC) |
| • luggage rack                | 74 / 483 / EEC |                |
| • speed limiter               | 92 / 24 / EEC  |                |
| • front underrun protection   | 2000 / 40 / EC |                |

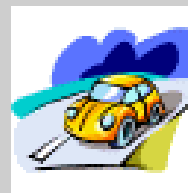


35

## - EC- Approval System -

### Directive 70/156/EEC

- Task in the type approval process
  - Member States
    - *notifies approval authorities*
    - *notifies technical services*
  - Approval authority
    - *is responsible for **ALL** aspects of type approval*
    - *appoints technical services*
    - *communicates with other approval authorities*
    - *verifies conformity of production arrangements*
    - *issues certificates*
    - *gives reports to the Commission*



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## - EC- Approval System -

### Directive 70/156/EEC

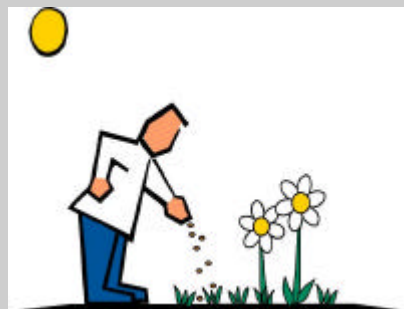
- **Task in the type approval process**
  - Technical services (test laboratories)
    - *fulfill EN 45000 or equivalent level*
    - *carry out type approval tests and inspections*
    - *report to approval authority*
  - Manufacturer
    - *is responsible to the approval authority for:*
      - type approval process
      - ensuring conformity of production

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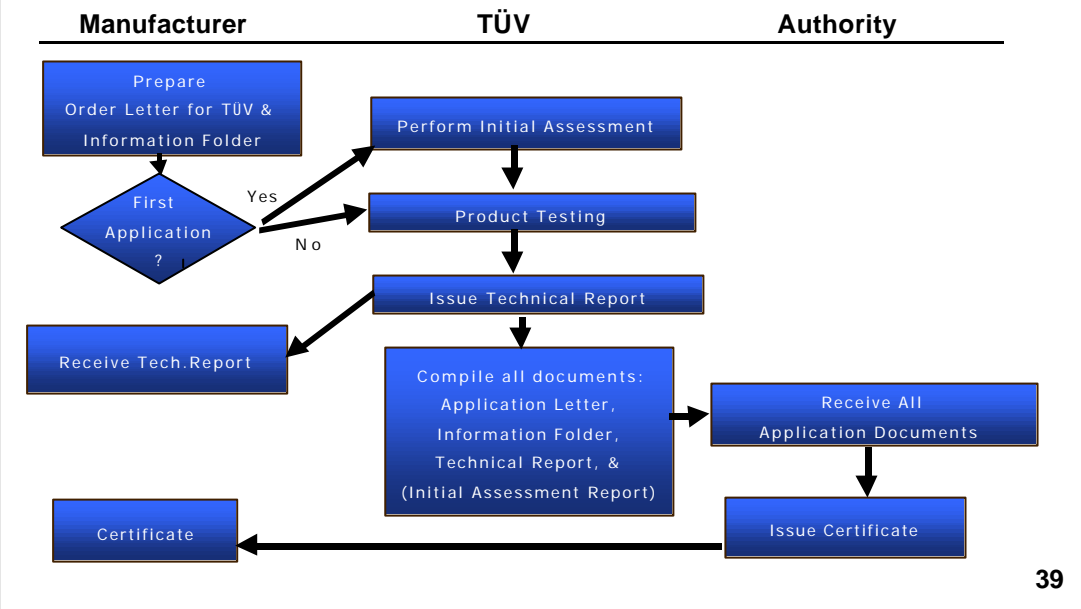
## - EC- Approval System -

### Main Steps of an approval assessment

- prepare application documents
- carry out test
- qualify as applicant
- decide representative
- application to authority
- certificate



## - EC- Approval System -



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## - StVZO/EC/ECE- Approval System -

### Your Competent and Reliable Partner

- You will be assisted by the engineers working in the Motor Vehicle Safety Department
- The engineers working in Europe, Asia or America are members of and supported by the test laboratory which resides in Cologne, Institute for Traffic Safety (ITS) of the TÜV Kraftfahrt GmbH
- This laboratory is accredited according to ISO 45001 and 9001 by the government of Germany



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## - StVZO/EC/ECE- Approval System -

**TÜV Laboratory is notified and has a close cooperation with several approval authorities:**

- KBA (Germany - E1)
- RDW (The Netherlands - E4)
- SNCT-H (Luxembourg - E13)
- VCA (United Kingdom - E11)
- The Authority of Belgium (E6)
- NSAI ( National Standards Authority of Ireland - E24)



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## - EC- Approval System -

### **Quality management in approval process**

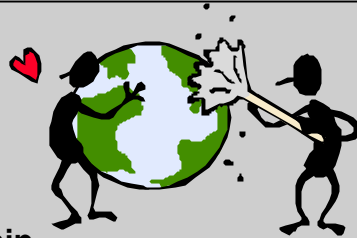
- **source:** Annex X of frame directive 70 / 156 / EEC (equivalent to general procedures mentioned in last amended provision of Geneva Treaty)
- **keywords and tasks:**
  - initial assessment (approval authority)
    - ***assess quality management systems***
    - ***assess manufacturer's potential and reliability***
  - product conformity arrangements (manufacturer)
    - ***ensure conformity to the approved type***
  - continued verification arrangements (approval authority)
    - ***verify approval subject and product related controls***

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## - ECE- Regulation System -

### ECE- Regulation

- Geneva agreement 1958
- link to United Nations
- global network of trust
- reciprocal recognition
- volunteer membership/partnership
- economic interests for Europe and the whole world
- development of acceptable technical standards
- enforce technical progress



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## - ECE- Regulation System -

### ECE- Regulation

- Extention of the 1958 Agreement (1998) unlimited
  - Membership of regional economic integration organization like the European Community
  - Membership of states located outside of the geographical area of Europe like Japan, China ...e.t.c.
- Applicability of technical regulations adjustable to national needs
  - contracting parties may select from entirety of regulations
  - accepted regulations can be cancelled individually
- Regulates only the type approval of components/systems and does not provide rules for whole vehicle type approval

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## - ECE - Regulation System -

### 1958 Agreement



- amended in 1998
- frame for the more than 100 subordinated ECE-regulations
- notification of a new regulation or an amendment by the General Secretary of UN in New York
- Annex I
  - Administrative Committee (AC 1 & 2) (vote on new / amended regulations)
  - acknowledgement and accreditation of test labs
- Annex II
  - conformity of production (COP) → 70 / 156 / EEC, Annex X

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## - ECE- Regulation System -

### The contracting parties of the ECE- System

NO.	Country	ECE Symbol	NO.	Country	ECE Symbol
1	Germany	E1	20	Portugal	E21
2	France	E2	21	Russian Federation	E22
3	Italy	E3	22	Greece	E23
4	The Netherlands	E4	23	Ireland	E24
5	Sweden	E5	24	Croatia	E25
6	Belgium	E6	25	Slovenia	E26
7	Hungary	E7	26	Slovakia	E27
8	Czech Republic	E8	27	Belarus	E28
9	Spain	E9	28	Estonia	E29
10	Yugoslavia	E10	29	Bosnia and Herzegovina	E31
11	United Kingdom	E11	30	Latvia	E32
12	Austria	E12	31	Bulgaria	E34
13	Luxembourg	E13	32	Turkey	E37
14	Switzerland	E14	33	The former Yugoslav Republic of Macedonia	E40
15	Norway	E16	34	European Community	E42
16	Finland	E17	35	Japan	E43
17	Denmark	E18	36	Australia	E45
18	Romania	E19	37	Ukraine	E46
19	Poland	E20			

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- ECE - Regulation System -
- EC - Approval System -



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- ECE- Regulation System -

#### The United Nations subsidiary bodies:

#### Economic and Social Council



Europe	ECE = Economic Commission for Europe
Africa	ECA
Asia / Pacific	ESCAP
Latin America and Caribic	ECLAC
West- Asia	ESCWA

ECE.....Inland Transport Committee..... (Construction of Vehicles)/  
Development and Harmonization of Vehicle Regulations..... World  
Forum for Harmonization of Vehicle Regulations(WP.29)

Six Working Groups

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## - ECE- Regulation System -

### WP.29 World Forum for Harmonization of Vehicle Regulations( WP.29)



The six working groups:

WP.29 - GRB - Working Party on Noise

WP.29 - GRE - Working Party on Lighting and Light- Signalling

WP.29 - GRPE- Working Party on Pollution and Energy

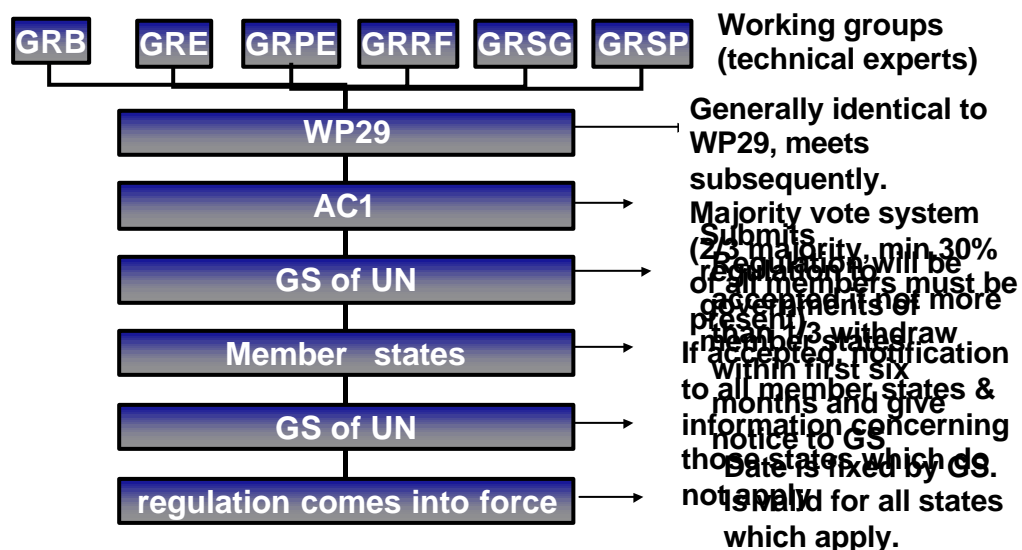
WP.29 - GRRF- Working Party on Brakes and Running Gear

WP.29 - GRSG- Working Party on General Safety Provision

WP.29 - GRSP- Working Party on Passive Safety

## - ECE - Regulation System -

### Legislation in ECE



## - ECE- Regulation System -

### TRANSPORT DIVISION STAFF MEMBERS

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Palais des Nations

CH-1211 Geneva 10

Telex: 41.29.62 UNO CH

Phone (+41 22) 907 2400

Fax: (+41 22) 917 00 39 / 00 89

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Mr. E. CIOTTI	72431 403		<a href="mailto:enrico.ciotti@unece.org">enrico.ciotti@unece.org</a>
Miss M. FERRAND	72424 412-3		<a href="mailto:monique.ferrand@unece.org">monique.ferrand@unece.org</a>
Mrs. V. MERIBOUT	74031 412-4		<a href="mailto:valerie.meribout@unece.org">valerie.meribout@unece.org</a>

##### Technology section



Development and Harmonization of Vehicle Regulations (former: Construction of Vehicles)

Mr. J. JERIE	72422 420		<a href="mailto:jan.jerie@unece.org">jan.jerie@unece.org</a>
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Mr. A. ERARIO	72402 412-1		<a href="mailto:antonio.erario@unece.org">antonio.erario@unece.org</a>
Mrs E. SISANTE-SPAETI	72491 412-2		<a href="mailto:elvira.sisante@unece.org">elvira.sisante@unece.org</a>
Mrs. N. ENONLER	71112 403		<a href="mailto:nelly.enonler@unece.org">nelly.enonler@unece.org</a>

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## - ECE- Regulation System -

### Comparison EC versus ECE

Item	EC	ECE
Origin	European trade, political unification	UN, global trust
Area of appointment	Member States EU	Whole Europe (and more)
Place of action	Brussels	Geneva
Membership	restricted	Open
New provisions	General need (Commission)	Min. 2/3 majority of contracting parties present and voting
Application	obligation	Voluntary
Scope of application	All existing and forthcoming directives	Selection from entirety of regulations
Whole vehicle approval	yes	No
Languages	All (member states)	French, English & Russian
Standards	'directive'	'regulation'
Holder of approval	manufacturer	Manufacturer
Definition of 'manufacturer'	Person or body responsible for all aspects of type approval	Organization with technical responsibility
Indicator for approvals & approval marks		

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## - Global Agreement -



The main automotive standards used in the todays world

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## - Global Agreement -

UNITED NATIONS  
AGREEMENT CONCERNING THE ESTABLISHING OF **GLOBAL TECHNICAL REGULATIONS** FOR WHEELED VEHICLES; EQUIPMENT AND PARTS WHICH CAN BE FITTED AND / OR BE USED ON WHEELED VEHICLES

DONE AT GENEVE ON 25 JUNE 1998

ECE/TRANS/132

The above agreement entered into force on **25 August 2000**, the 30th day following the date on which at least 8 countries and / or regional economic integration organizations have become contracting parties to the agreement.

On 26 July 2000 the Russian Federation became the eighth contracting party to the agreement.

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## - Global Agreement -

### THE ARTICLES/ ANNEXES OF THE GLOBAL AGREEMENT

Article 1,	Purpose
Article 2,	Contracting parties and consultative status
Article 3,	Executive committee
Article 4,	Criteria for technical regulations
Article 5,	Compendium of candidate global technical regulations
Article 6,	Registry or global technical regulations
Article 7,	Adoption, and notification of application, of established global technical regulations
Article 8,	Issue resolution
Article 9,	Becoming a contracting party
Article 10,	Signature
Article 11,	Entry into force
Article 12,	Withdrawal from agreement
Article 13,	Amendment of agreement
Article 14,	Depositary
Article 15,	Extension of agreement to territories
Article 16,	Secretariat
Annex A,	Definitions
Annex B,	Composition and rules of procedure of the executive committee

## - Global Agreement -

### Contracting Party

Canada  
USA  
Japan  
France  
United Kingdom  
European Community  
Germany  
Russian Federation  
Republic of South Africa  
Spain

### Signature/ ratification/ acceptance/ accession date

22 June 1999  
26 July 1999  
03 August 1999  
04 January 2000  
10 January 2000  
15 February 2000  
11 May 2000  
26 July 2000  
?  
?

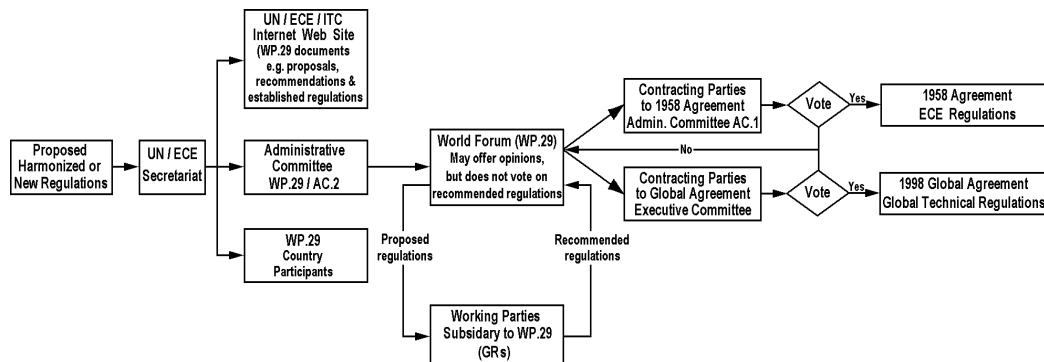
### Application of the agreement on

25 August 2000  
25 August 2000  
25 August 2000  
25 August 2000  
25 August 2000  
25 August 2000  
25 August 2000  
25 August 2000  
25 August 2000  
?  
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## - ECE- Regulation System -

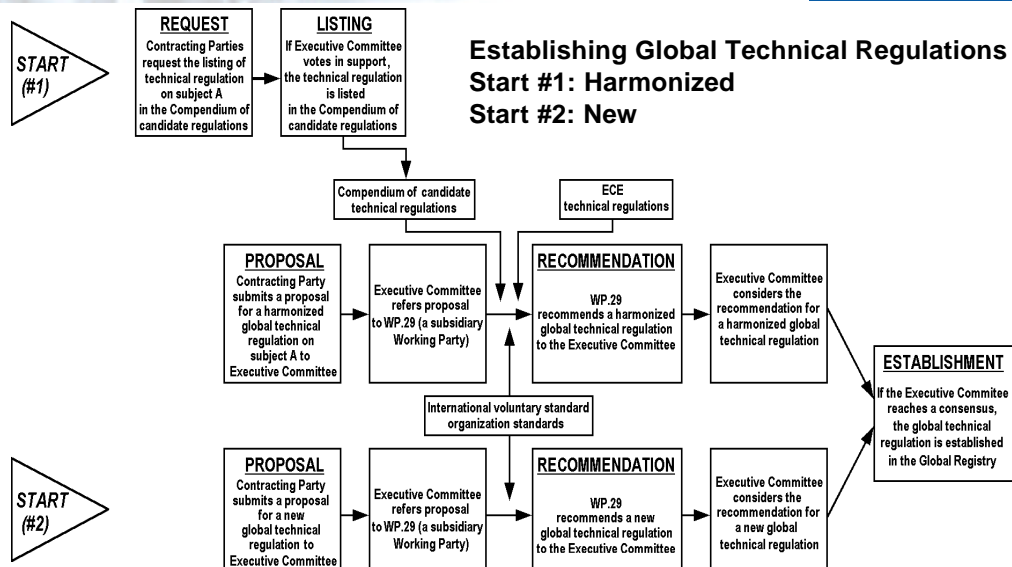
### UN/ECE World Forum 29 Consideration and Establishment of Regulations



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## - Global Agreement -

### Establishing Global Technical Regulations Start #1: Harmonized Start #2: New



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## Global Agreement

- **History:**
  - USA declared not to join the ECE 1958 agreement
- **Why this new agreement:**
  - To have a common basis to harmonize alternative requirements for all greater vehicle manufacturers and the respective states.
- **Difference to ECE 1958 agreement:**
  - The Global Agreement does not provide the mutual Recognition of approvals. It will exist parallel to the 1958 agreement.
- **Based where:**
  - This Global Agreement was developed and came into force via the WP 29 (World Forum For Harmonization of Vehicle Regulations)
- **Internet:**
  - [TRANS/WP.29/2000/65](#); dated 29 August 2000

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## General Information:

U.S.A: <http://www.nhtsa.gov>  
<http://www.dms.dot.gov>

EC: <http://www.europa.eu.int/eur-lex/de/index.htm>  
[http://www.europa.eu.int/eur-lex/de/com/reg/de\\_register\\_133010.html](http://www.europa.eu.int/eur-lex/de/com/reg/de_register_133010.html)  
<http://www.eudor.com>

ECE: <http://www.unece.org/trans/main/welcwp29.html>

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Homologation Services



TÜV Rheinland/  
Berlin-Brandenburg,  
Seoul office, since 1987



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Homologation Services

**Introduction of TÜV Rheinland Korea Ltd. /  
TÜV Rheinland Group and its services, cooperating European  
authorities, test & certification cost etc.:**

Based in Germany and with 200 offices in more than 60 countries, TÜV Rheinland is an internationally active, private organization with over 130 years of experience in the field of certifying and testing technical installations and products.

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Homologation Services


Mobility and Transport Department (Seoul+Daegu)

Two secretaries and nine government-authorized experts are in charge to service our clients in the fields of motor vehicle testing, motorcycle testing, agricultural tractor testing and testing of their parts or components in accordance with German requirements, Directives issued by the Council of European Community (EC) and Economic Commission of Europe (ECE).

Also Automotive related research studies and consulting projects are handled.

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Homologation Services

Mobility and Transport Dept. represented in Tokyo, Osaka, Seoul, Taipei etc., now has a staff over 30 engineers involved in the testing of motor vehicles, motor cycle and their parts or components in accordance with International and German standards. Our clients are leading Asian and European manufacturers of motor vehicle, motor cycle and parts.

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The engineers working in this department are **officially authorized by the governments in Germany, Netherland, and Luxembourg** to carry out type approval tests for motor vehicle, motorcycle and their parts. The tests are performed according to international standards issued by the European Economic Community (EEC) or Economic Commission for Europe (ECE) as well as for German National Type Approval (NTA). Additionally the reputation of our work is so that other countries like Austria, Chile, Turkey or Israel do accept our test reports.