



ITU Training on Conformance and Interoperability for AFR Regions



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New approach directives

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International certification

meet different national certification or approval criteria

promote harmonization of the national standards with international ones



Reduce obstacles to international trade

cooperation among accepted NCBs worldwide



"one product, one test, one mark"



- 1. New Approach directives**
- 2. Harmonised standards**
- 3. The R&TTE directive**
- 4. The EMC directive**
- 5. CE Marking**

- 1. New Approach directives**
2. Harmonised standards
3. The R&TTE directive
4. The EMC directive
5. CE Marking



- A directive is a legislative act of the European Union ([link](#))
- which requires member states to achieve a particular result
- without dictating the means of achieving that result.

- The need for CE Marking
- New Approach Directives
 - ✓ Eliminate differences in laws therefore remove technical barriers to trade
 - ✓ Prescribe the Essential requirements for Health, Safety, ..
 - ✓ Member states transpose directives and harmonized standards into their national requirements
 - ✓ Third party intervention is not mandatory
 - ✓ Manufacturer Self conformity Declaration
 - ✓ Voluntary Use of Standards
 - ✓ CE Label as the indication of compliance
- [CE marking process](#)

Terms & Definitions

- European Directive

- ✓ Legal Document adopted by EC Council of Ministers
- ✓ Must be adopted into National Law by each EC member state

- European standards (EN)

- ✓ Harmonized Standards: Common Standards used for determining conformity
 - **Committee process**
 - **ENs based on existing standards (CISPR, IEC, ETSI)**
 - **Application of standards is not mandatory**
- ✓ Must be adopted into National Standards by each EC Member state

Terms & Definitions

- **Notified Body**
 - ✓ “Notified” means that the organization has been “officially announced” to the EC and other states by National Authority

- **IEC**
 - ✓ International Electrotechnical Commission

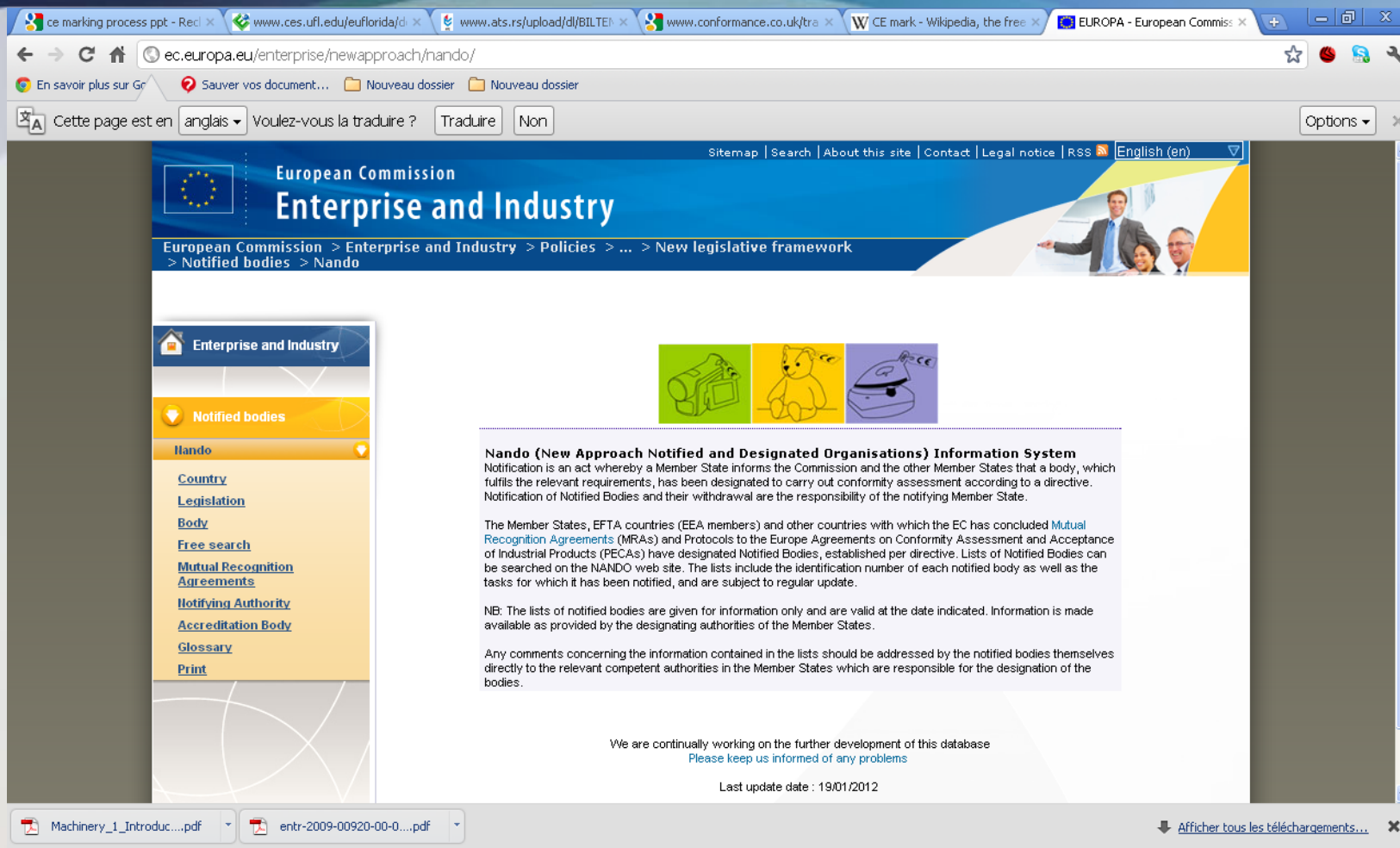
- **CENELEC**
 - ✓ European Committee for Electrotechnical Standardization

- **ETSI**
 - ✓ European Telecommunications Standards Institute



Essential requirements

- the requirements that products must meet to be put on the market.
- They are mandatory.
- They define the results to be attained, or the risks to be dealt with, but do not specify the technical solutions for doing so;
- suppliers are free to choose how the requirements are to be met.



The screenshot shows a web browser window displaying the European Commission Enterprise and Industry Nando website. The browser's address bar shows the URL <http://ec.europa.eu/enterprise/newapproach/nando/>. The page header includes the European Commission logo and the text "Enterprise and Industry". A navigation breadcrumb trail reads: "European Commission > Enterprise and Industry > Policies > ... > New legislative framework > Notified bodies > Nando".

The main content area features three icons: a green icon of a machine, a yellow icon of a teddy bear, and a purple icon of a CE mark. Below these icons is the section title "Nando (New Approach Notified and Designated Organisations) Information System". The text explains that notification is an act where a Member State informs the Commission and other Member States that a body, which fulfills the relevant requirements, has been designated to carry out conformity assessment according to a directive. It also states that the notification of Notified Bodies and their withdrawal are the responsibility of the notifying Member State.

The text continues: "The Member States, EFTA countries (EEA members) and other countries with which the EC has concluded Mutual Recognition Agreements (MRAs) and Protocols to the Europe Agreements on Conformity Assessment and Acceptance of Industrial Products (PECAs) have designated Notified Bodies, established per directive. Lists of Notified Bodies can be searched on the NANDO web site. The lists include the identification number of each notified body as well as the tasks for which it has been notified, and are subject to regular update."

A note (NB) states: "The lists of notified bodies are given for information only and are valid at the date indicated. Information is made available as provided by the designating authorities of the Member States."

Another note states: "Any comments concerning the information contained in the lists should be addressed by the notified bodies themselves directly to the relevant competent authorities in the Member States which are responsible for the designation of the bodies."

At the bottom of the page, it says: "We are continually working on the further development of this database. Please keep us informed of any problems." and "Last update date : 19/01/2012".

The browser's taskbar at the bottom shows two PDF files: "Machinery_1_Introduc....pdf" and "entr-2009-00920-00-0....pdf". There is also a download button labeled "Afficher tous les téléchargements..." with a close icon.

<http://ec.europa.eu/enterprise/newapproach/nando/>

Fundamental Principals

New approach directives are based on four fundamental principals:

- Legislative harmonization
- Technology advance and know-how
- Voluntary standards;
- Conformity presumption to essential requirements

Specificities

- The New Approach deals with
 - ✓ large families of products : e.g. machinery, construction products, toys, etc....,
 - ✓ or horizontal risks : such as electromagnetic compatibility or electric safety, as opposed to the product-based approach used under the Old Approach;

Included Directives

- It is quite possible that a product may be governed by more than one directive.
- one can easily imagine the simultaneous application of the Electromagnetic Compatibility (EMC) Directive and the low voltage Directive (LVD)

European directives

- Directives

- ✓ Low Voltage (2006/95/EC)
- ✓ Toy Safety (88/378/EEC) Amended by 93/68/EEC
- ✓ Construction Products (89/106/EEC) Amended by 93/68/EEC
- ✓ EMC (2004/108/EC)
- ✓ Machinery (89/392/EEC) Amended by 93/68/EEC
- ✓ Personal Protective Equipment (89/686/EEC)
- ✓ R&TTE (1999/5/CE)
- ✓ Medical Devices (93/42/EEC)
- ✓ Explosive Atmospheres (94/9/EEC)

Which Directives Apply?

- Specific Directives
- General Directives
- Explicit exclusions in EMC Directive
 - ✓ Aeronautical products, parts and appliances covered by 1592/2002, 216/2008
 - ✓ Radio Transmitters covered by 1999/5/EC
 - ✓ Amateur radio equipment (non-commercially available)
- Exclusions for equipment covered by other specific directives
 - ✓ Medical Devices
 - ✓ R&TTE
 - ✓ Motor Vehicles
 - ✓ Agricultural and Forestry Tractors

- Putting into market is possible only if the product conforms to all applicable directives
- Conformity evaluation must be done with respect to essential requirements of all the applicable directives

Notification

- Notification is an act whereby a Member State informs the Commission and the other Member States that a body, which fulfils the relevant requirements, has been designated to carry out conformity assessment according to a directive.

Examples of Notified Bodies

Body type	Name ▲	Country ▲
▶ NB 0026	AIB-VINÇOTTE INTERNATIONAL S.A.	Belgium
▶ NB 0028	INSTITUTO DE SOLDADURA E QUALIDADE	Portugal
▶ NB 0038	Lloyd's Register Verification Limited	United Kingdom
▶ NB 0063	Kiwa Nederland B.V.	Netherlands
▶ NB 0069	UNION TECHNIQUE DE L'AUTOMOBILE, DU MOTOCYCLE ET DU CYCLE	France
▶ NB 0071	Laboratoire National de métrologie et d'Essais (LNE)	France
▶ NB 0080	INSTITUT NATIONAL DE L'ENVIRONNEMENT INDUSTRIEL ET DES RISQUES	France
▶ NB 0081	LABORATOIRE CENTRAL DES INDUSTRIES ELECTRIQUES	France
▶ NB 0086	BSI	United Kingdom
▶ NB 0091	TÜV TECHNISCHE ÜBERWACHUNG HESSEN GMBH	Germany
▶ NB 0096	SGS, TECNOS, S.A.	Spain
▶ NB 0123	TÜV SÜD Product Service GmbH	Germany
▶ NB 0168	BRITISH APPROVALS BOARD FOR TELECOMMUNICATIONS	United Kingdom
▶ NB 0197	TÜV Rheinland LGA Products GmbH	Germany
▶ NB 0341	SECRETARÍA DE ESTADO DE TELECOMUNICACIONES Y PARA LA SOCIEDAD DE LA INFORMACION	Spain
▶ NB 0344	DEKRA Certification B.V.	Netherlands
▶ NB 0359	INTERTEK TESTING & CERTIFICATION LTD	United Kingdom
▶ NB 0366	VDE - Prüf- und Zertifizierungsinstitut GmbH	Germany
▶ NB 0370	LGAI TECHNOLOGICAL CENTER, S. A./Applus	Spain

http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=129141&type_dir=NO%20CPD&pro_id=99999&prc_id=99999&ann_id=99999&prc_anx=99999

- Find the applied directives for the concerned product
- Choose the best evaluation method to attest conformity
- Find and apply the harmonised standard(s)
 - ✓ http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/electromagnetic-compatibility/index_en.htm
- Eventually contact third party organism
- Establish declaration of conformity and technical construction file
- Appose CE marking
- Put the product into market
- Follow the manufacturing process

1. New Approach directives
- 2. Harmonised standards**
3. The R&TTE directive
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Principal



the harmonised standard(s)

Under New Approach, there is no obligation to use EN standards

 presumption of conformity with the essential requirements

Standards

- Three kinds of standards:
 - ✓ Product standards (e.g. CISPR22/EN 55022 (ITE), ETS 300 342-1 (GSM))
 - ✓ Generic standards (e.g. IEC 61000-6-x)
 - ✓ Fundamental standards (e.g. CISPR 16, IEC 61000-4-x)
- Major standardisation groups for commercial standards:
 - ✓ CISPR, IEC, ISO, ITU as international groups
 - ✓ CENELEC, ETSI in Europe
 - ✓ ANSI, FCC, SAE in USA

EMC Test Standards

- Product specific test standards establish requirements and typically point to test method standards. Normally include:
 - ✓ Radiated Emissions – CISPR 11 or CISPR 22
 - ✓ Conducted Emissions – CISPR 11 or CISPR 22
 - ✓ Harmonic Emissions – IEC 61000-3-2
 - ✓ Flicker – IEC 61000-3-3
 - ✓ Electrostatic Discharge – IEC 61000-4-2
 - ✓ Radiated Immunity – IEC 61000-4-3
 - ✓ Electrically Fast Transient Immunity – IEC 61000-4-4
 - ✓ Surge Immunity – IEC 61000-4-5
 - ✓ Conducted Immunity – IEC 61000-4-6
 - ✓ Magnetic Immunity - IEC 61000-4-8
 - ✓ Voltage dips/interrupts – IEC 61000-4-11

- Official Journal

- ✓ EMC, LVD, MSD
 - “Europa” web site for latest rev.
- ✓ Order of Use
 - Product Specific Standard
 - Generic Standard
 - Basic Standard
- ✓ Look for Date of Cessation of Presumption of Conformity.

<http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards>

For each directive, the list of harmonised standards is periodically updated

25.9.2007 EN Official Journal of the European Union C 225/1

IV
(Notices)

NOTICES FROM MEMBER STATES

Commission communication in the framework of the implementation of Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC
(Text with EEA relevance)
(Publication of titles and references of harmonised standards under the directive)
(2007/C 225/01)

European standardisation organisation (*)	Reference and title of the standard (and reference document)	Reference of the superseded standard	Date of cessation of presumption of conformity of the superseded standard Note 1
Ceneltec	EN 50065-1:2001 Signalling on low-voltage electrical installations in the frequency range 3 kHz to 148,5 kHz — Part 1: General requirements, frequency bands and electromagnetic disturbances	EN 50065-1:1991 + A1:1992 + A2:1995 + A3:1996 Note 2.1	Date expired (1.4.2003)
Ceneltec	EN 50065-2-1:2003 Signalling on low-voltage electrical installations in the frequency range 3 kHz to 148,5 kHz — Part 2-1: Immunity requirements for mains communications equipment and systems operating in the range of frequencies 95 kHz to 148,5 kHz and intended for use in residential, commercial and light industrial environments Amendment A1:2005 to EN 50065-2-1:2003	Relevant generic standard(s) Note 2.3 Note 3	Date expired (1.10.2004) 1.7.2008
Ceneltec	EN 50065-2-2:2003 Signalling on low-voltage electrical installations in the frequency range 3 kHz to 148,5 kHz — Part 2-2: Immunity requirements for mains communications equipment and systems operating in the range of frequencies 95 kHz to 148,5 kHz and intended for use in industrial environments Amendment A1:2005 to EN 50065-2-2:2003	Relevant generic standard(s) Note 2.3 Note 3	Date expired (1.10.2004) 1.7.2008
Ceneltec	EN 50065-2-3:2003 Signalling on low-voltage electrical installations in the frequency range 3 kHz to 148,5 kHz — Part 2-3: Immunity requirements for mains communications equipment and systems operating in the range of frequencies 3 kHz to 95 kHz and intended for use by electricity suppliers and distributors Amendment A1:2005 to EN 50065-2-3:2003	Relevant generic standard(s) Note 2.3 Note 3	Date expired (1.8.2004) 1.7.2008

1. New Approach directives
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Introduction

- The market for Radio & Telecom Terminal Equipments (R&TTE) exceeds 30 B€ and is undergoing rapid growth.
- It was regulated through an EU Directive (98/13/EC) and more than 1000 national approval regulations.
- As of 8 April 2000, the [R&TTE Directive](#) replaces these regulations and governs the marketing and use of R&TTE equipment.
- <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0005:en:NOT>

Typical products

Typical products, which are covered by the Directive, are:

- ✓ Radio terminals: GSM handsets.
- ✓ Other radio equipment: GSM base stations, car-door openers and other short range radio devices.
- ✓ Fixed network terminal equipment: normal analogue telephones, XDSL terminals, cable and PC modems.

Manufacturers Declaration of Conformity

- Introduction of manufacturers' declaration of conformity
- Assessment of the conformity of a product with the requirements of the Directive **becomes a responsibility for the manufacturer.**



No need to obtain an approval certificate from an official body after having passed tests in a legally recognized laboratory.

MINIMUM Requirements

- Terminal access requirements have been removed: fixed network terminal equipment therefore only needs to comply with
 - ✓ **Health and Safety** requirements:
 - Health : as per EMF recommendation 1999/519/CE
 - Safety : as per Directive 2006/95/CE (LVD) but with the lower limit removed. (Article 3.1)
 - ✓ **EMC** requirements: as per Directive 2004/108/CE (Article 3.1)
 - ✓ Radio equipment needs to effectively **use the spectrum** and not cause harmful interference. (Article 3.2)

Applied standards

- **Radio** : EN 300 328 + ERC 70-03 recommandation
- **EMC** : EN 301 489-17 & EN 301 489-01
- **Security** : EN 60950
- **Health** : EN 50364



Scope: Complete Coverage of the Sector



- The Directive replaces **national regimes**.
- Any problems caused by the fact that the frequency spectrum in the Community is not fully harmonised are handled through specific provisions in the Directive.



interfaces

- **Obligation for network operators to publish their interfaces**
- **allowing any manufacturer to construct terminal equipment to be attached to that network.**

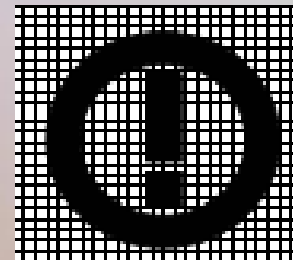
Class 1:

- **Radio equipment and telecommunications terminal equipment which can be placed on the market and be put into service without restrictions.**
- **This class will be referred to as “Class 1”. An Equipment Class Identifier is not defined for this class of equipment.**

Equipment Class Identifiers

Class 2:

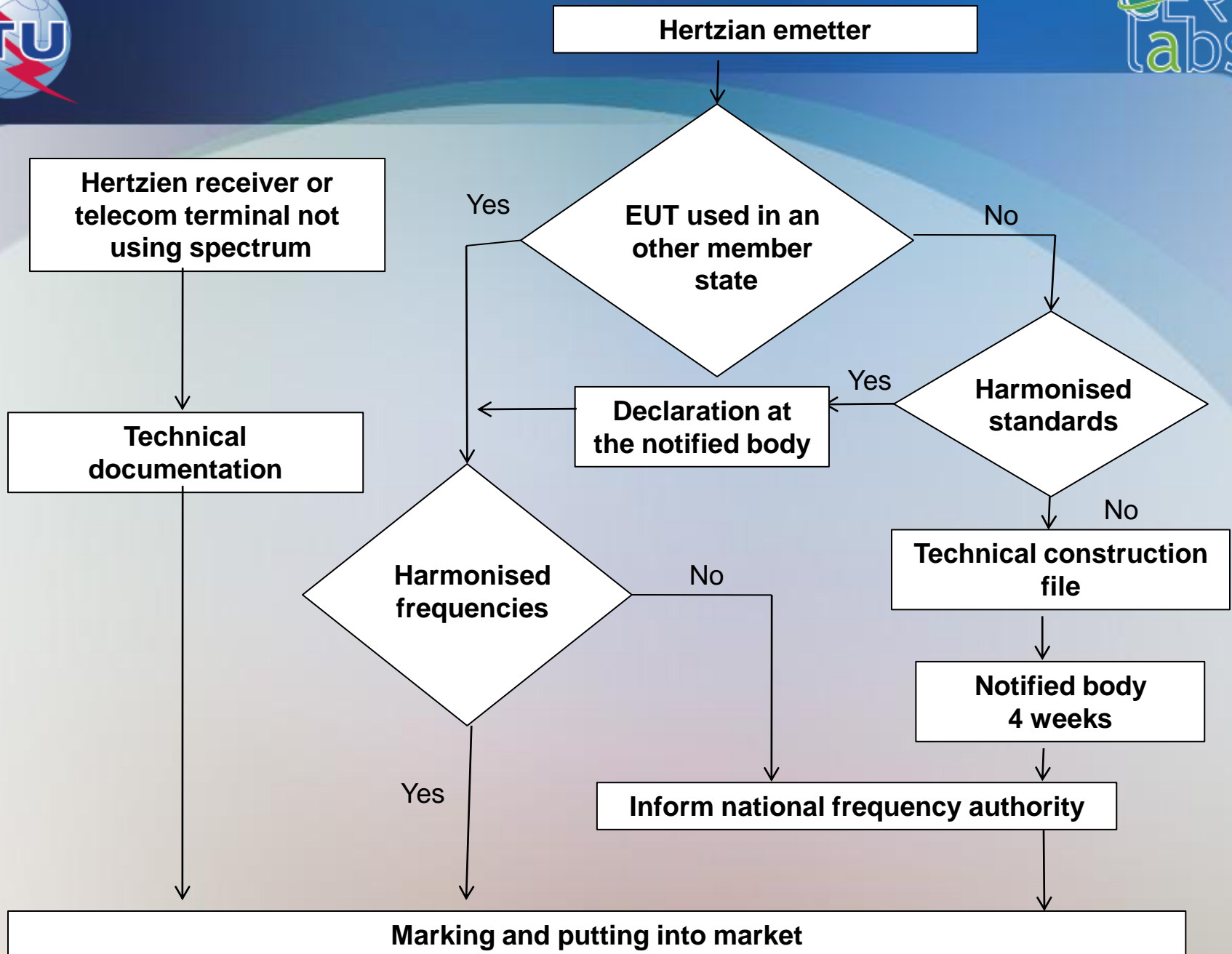
- **R&TTE equipment for which Member States apply restrictions on the putting into service**
- **or for which Member States apply restrictions on the placing on the market.**
- **This class will be referred to as “Class 2”. The following Equipment Class Identifier or “alert sign” is defined for equipment within this class:**





Putting Into Market

- Comply to essential requirements
- Respect of the national requirements





Technical Construction File



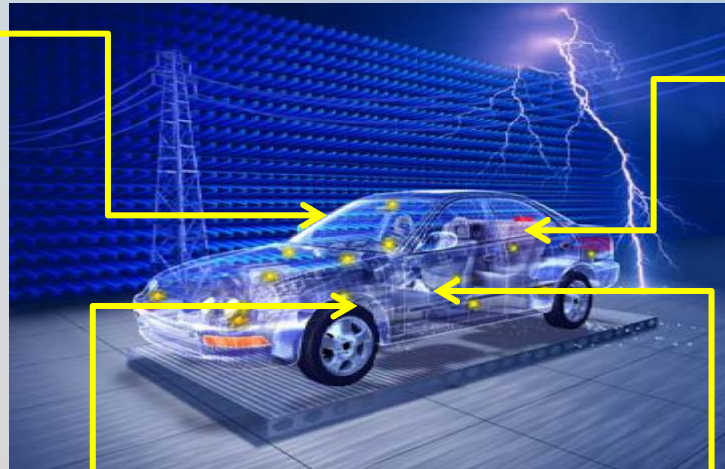
1. Product description
2. Drawings and schema of the product
3. User sheet
4. Applied harmonised standards or adopted solution to meet essential requirements
5. Results of computation and simulation at the conception
6. Test report

1. New Approach directives
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Real World Phenomena



RF transmitters



Mobile phones



ESD

- External Impacts
- Internal Impacts
- Human Impacts



Lightning

Products Concerned by EMC Tests



Radio & Telecom equipments

ManufacturerTender books



Aerospace components



Automotive components



Medical equipments

Equipments



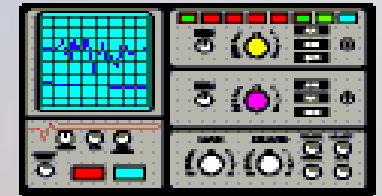
Information Technology Equipments (ITE)



Houshold equipments



Consumer Equipment



Laboratory equipments

- **Title**

- ✓ Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC

Scope

- **Equipment**

- ✓ Apparatus

- ┆ Electrical and electronic appliance
- ┆ Component (component intended for incorporation by the end user)

- ✓ Fixed installations

- ┆ Many appliances or components assembled and installed at a predefined location

- **Not covered**

- ✓ R&TTE equipment (Directive 1999/5/EC)
- ✓ Radio equipment used by radio amateurs
- ✓ Equipments covered by other directives
- ✓ Apparatus or fixed installation classification
- ✓ EMC benign equipment

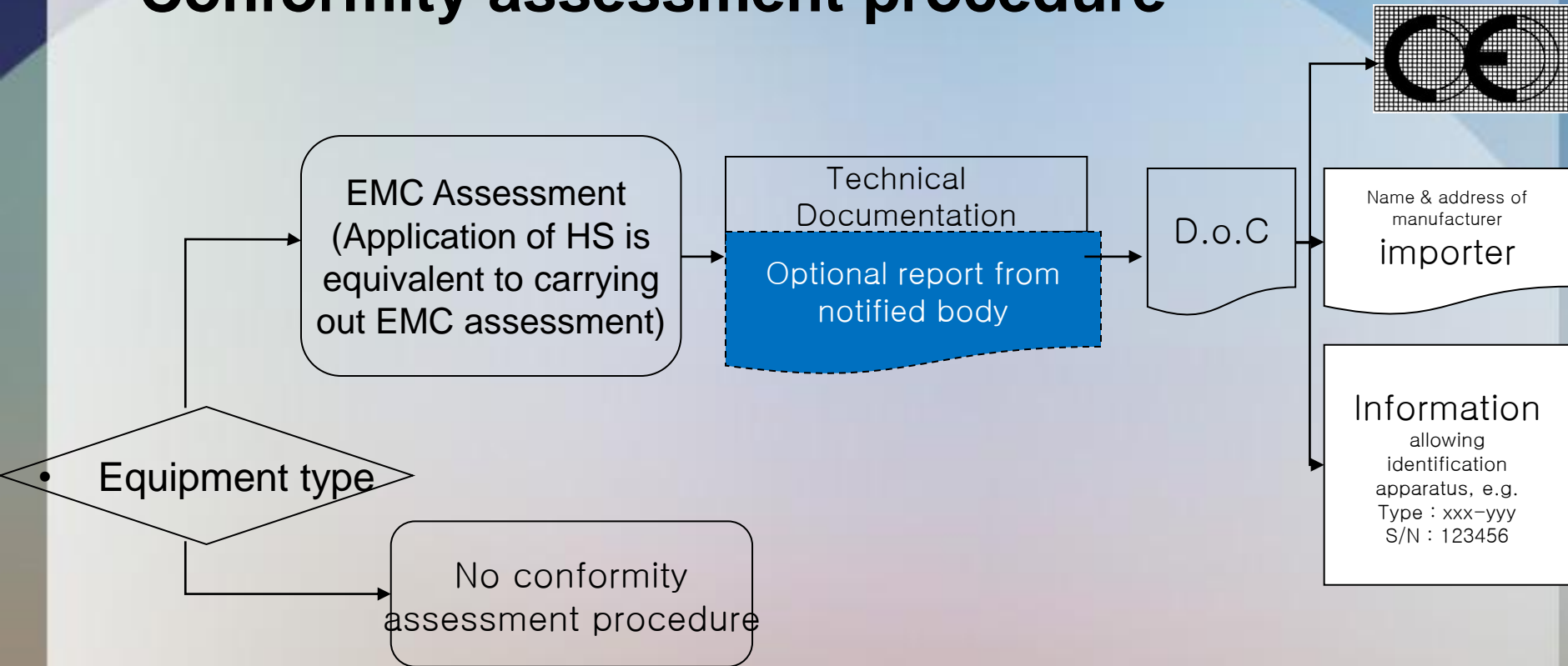


EMC Essential Requirements



- **EMC – Electromagnetic Compatibility**
 - ✓ The ability to operate in the intended environment without performance degradation
 - ✓ The ability to operate in the intended environment without interfering with operation of other equipment/systems

- Conformity assessment procedure**





2004/108/EC Directive - Changes

- **Clarification of scope and definitions**
- **Simplification of compliance methods – DoC**
- **Elimination of mandatory NB/CB examinations**
- **Modified DoC supporting location of responsible parties by enforcement**
- **Requirement for unique product identification**
- **Clear treatment of fixed installations and their compliance obligations**

Example of declaration of conformity

*Example of a declaration of conformity
(in accordance with EN ISO/IEC 17050-1:2004)
for products falling under the EMC directive 2004/108/EC*

DECLARATION OF CONFORMITY (DoC)

Name and address of the manufacturer, and,
where applicable, of his authorized
representative within the Community:

Object of the declaration:
(type, batch, serial number
or any other information)

The above mentioned product complies with the essential requirements, which are specified in the directive 2004/108/EC on the approximation of the laws of the Member States relating to electromagnetic compatibility.

The product of the declaration described above is in conformity with the requirements of the following specifications:

Documents-No.:	Title:	Edition/Date of issue
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Additional information:

(Date of issue of the DoC)

(Identity and signature of responsible person)

Useful Links

- European Commission: http://ec.europa.eu/enterprise/electr_equipment/emc/index.htm
- EMC guideline of the directive 2004/108/EC: http://ec.europa.eu/enterprise/electr_equipment/emc/guides/emcguide_may2007.pdf
- Published harmonised standards in field of EMC: <http://ec.europa.eu/enterprise/newapproach/standardization/harmonised/reflect/emc.html>
- Notified bodies related to the EMC- directive 2004/108/EC: http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?function=directive.notifiedbody&dir_id=129141&type_dir=NO%20CPD&pro_id=99999&prc_id=99999&ann_id=99999&prc_anx=99999
- List of EMC contact points: http://ec.europa.eu/enterprise/electr_equipment/emc/contactpoints.htm

1. New Approach directives
2. Harmonised standards
3. The EMC directive
4. **CE Marking**

Definition

- The **CE mark** (abbreviation of french words: **Conformité Européenne**, meaning "European Conformity", formerly EC mark) is a mandatory conformity mark for products placed on the market in the European Economic Area (EEA).
- With the CE marking on a product the manufacturer ensures that the product conforms with the essential requirements of the applicable EC directives.

Rules

- **The manufacturer of a product affixes the CE marking to it but has to take certain obligatory steps before the product can bear CE marking.**
- **The manufacturer must**
 - ✓ carry out a conformity assessment,
 - ✓ set up a technical file
 - ✓ and sign an EC declaration of conformity.
- **The documentation has to be made available to authorities on request.**

Contributors

1. The manufacturer

The person who is responsible for designing and manufacturing a product with a view of placing it on the Community market on his own behalf.

In practice: under his own name

2. Authorised Representative

If manufacturer is not established in the EU, though not mandatory

3. Importer

4. Distributor

5. Assembler and Installer

6. Operator (User)

Responsability

- The manufacturer/importer/ distributor is **legally responsible** for ensuring that the product confirms to the requirements of the directive and for applying CE Marking.



Declaration of Conformity



The DoC must include:

1. manufacturer's details (name and address, et c.);
2. essential characteristics the product complies;
3. any European standards and performance data;
4. if relevant the identification number of the Notified Body;
5. and a legally binding signature on behalf of the organization.

CE Marking

- **Implementation of the CE Marking:**

- ✓ Must be affixed to:
 - Product
 - Packaging
 - Instructions for use, OR
 - Guarantee certificate
- ✓ Can be used with other marks providing they do not reduce the visibility and legibility of the mark
- ✓ The marking may include:
 - The identification of a notified body involved in assessment



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