DECISION No 768/2008/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008 on a common framework for the marketing of products

DECISION No 768/2008/EC

This Decision sets out the common framework of general principles and reference provisions for the drawing up of Community legislation harmonising the conditions for the marketing of products (Community harmonisation legislation).

This Decision also provides for:

- Requirements for CABs to be notified to the Commission
- Notification procedures
- Procedures for conformity assessment

Notifying authorities

- The notifying authority is responsible for the **assessment** and **notificatio**n of conformity assessment bodies;
- Can be carried out by a **national accreditation body** in accordance with Regulation (EC) No 765/2008;
- Must be a governmental entity or a legal entity that complies with the same requirements and have liability cover.

Notifying Authorities - Requirements

- No conflict of interest with CABs.
- Must have objectivity and impartiality
- Decision relating to notification is taken by competent persons different from those who carried out the assessment.
- Must not provide any CAB activities or consultancy services on a commercial or competitive basis.
- Must safeguard the confidentiality of the information it obtains.
- Must have sufficient number of competent personnel.

Notified Conformity Assessment Bodies

- Established under national law and have legal personality.
- Third-party body independent of the product it assesses.
- May be linked to a business association or professional federation if independent and no conflict of interest.
- Cannot not be linked to the products which they assess.
- Must not engage in any activity that may conflict with their independence of judgement or integrity.
- Activities of subsidiaries or subcontractors must not affect its confidentiality, objectivity or impartiality.

Notified Conformity Assessment Bodies

- Must be impartial and have adequate liability cover;
- Must carry out the conformity assessment activities:
  - with the highest degree of professional integrity;
  - with the requisite technical competence; and
  - be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities.
- Senior management remuneration must not be linked to the number or results of conformity assessments carried out.

Notified Conformity Assessment Bodies

- Policies and procedures that distinguish between tasks it carries out as a notified body and other activities;
- Personnel with sufficient technical knowledge and experience and appropriate equipment and facilities.
- Documented conformity assessment procedures appropriate for its size, structure, operating sector, degree of complexity of the product technology and the nature of the production.
- Necessary technical and administrative capacity.

CAB personnel competences

- Sound technical and vocational training;
- Satisfactory knowledge and adequate authority;
- Appropriate knowledge and understanding of:
  - the essential requirements,
  - the applicable harmonised standards, and
  - of the relevant provisions of Community harmonisation legislation and of its implementing regulations;
- Ability to draw up certificates, records and reports;
- Observe professional secrecy.

8

Conformity Assessment

- Where legislation requires conformity assessment, it may provide for that assessment to be carried out by ***public authorities, manufacturers or notified bodies.***
- Where the conformity assessment is to be carried out by public authorities, the legislation shall provide that the conformity assessment bodies on which those authorities rely for technical assessments ***must comply*** with the same criteria as those set out in this Decision for notified bodies.

Conformity Assessment Procedures

- Sets out the conformity assessment modules – A to H
- Their criteria for use:

  (a) appropriate to the type of product;

  (b) the nature of the risks

  (c) manufacturer choice if third party involvement is mandatory,

  (d) avoidance of imposing modules which would be too burdensome in relation to the risks

EU Conformity assessment modules

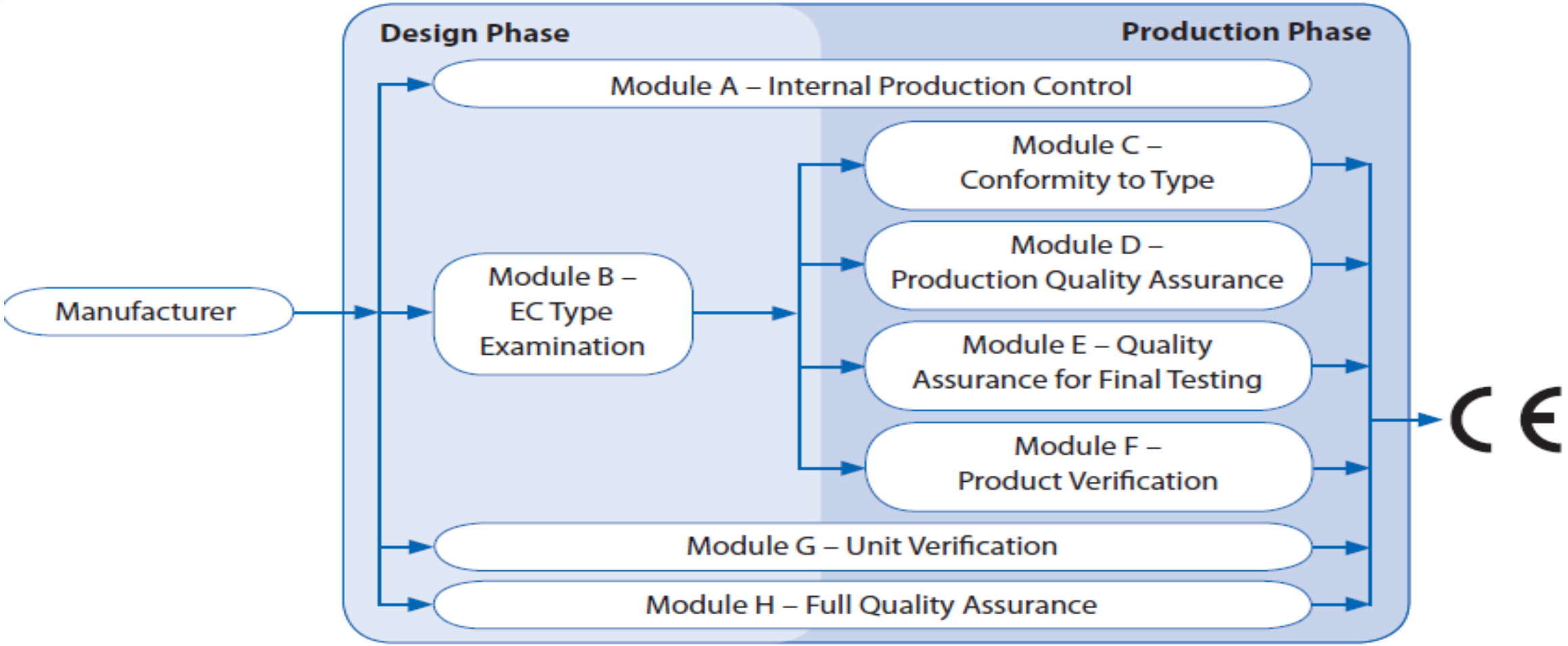
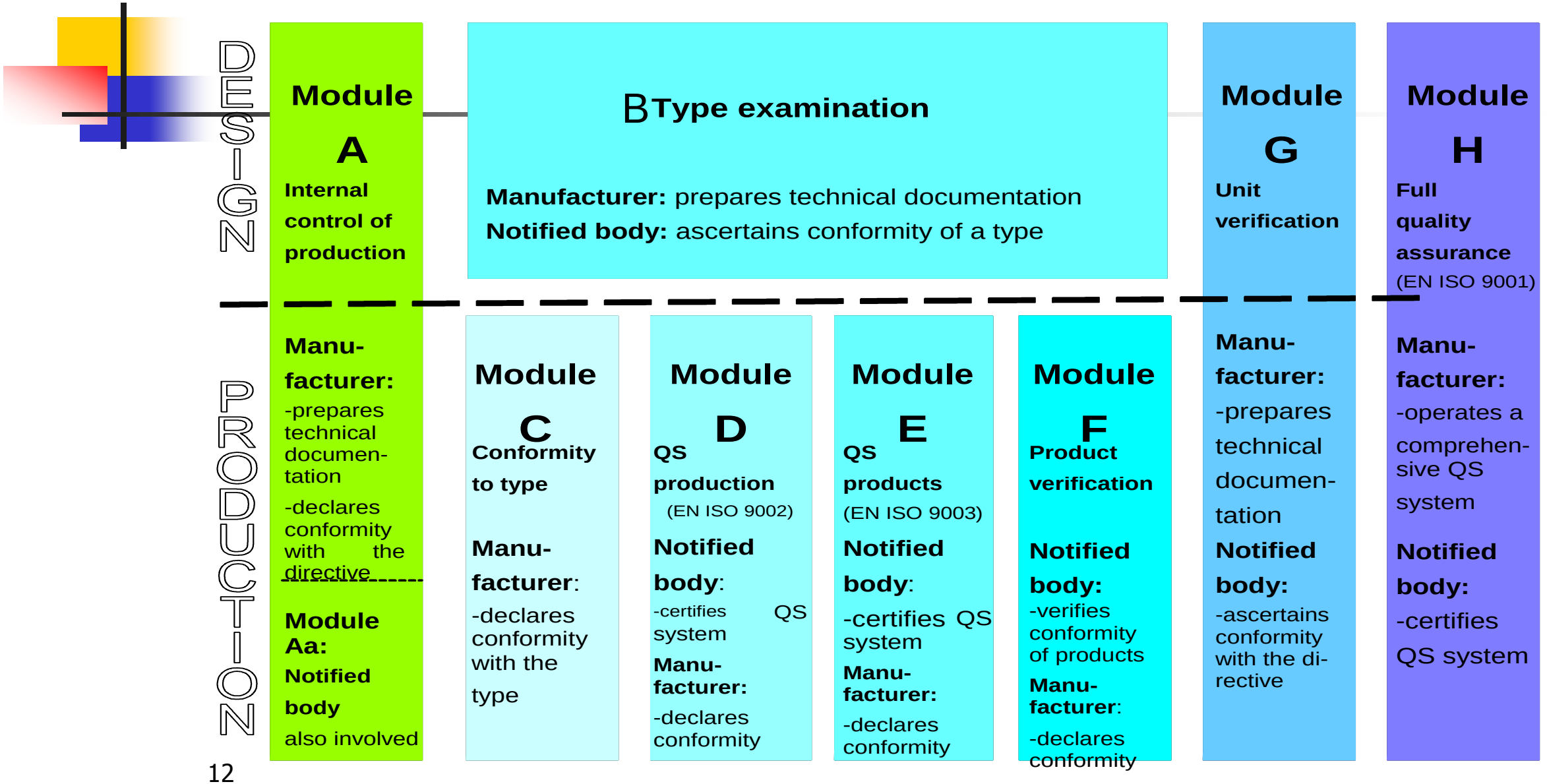


Figure 3: Modules of conformity assessment for CE marking.

Conformity assessment procedures of the new approach : the modules



Module A - Description

A - Internal production control

- *Covers both design and production.*
- *The manufacturer himself ensures the conformity of the products to the legislative requirements (no EU-type examination).*

A1 - Internal production control plus supervised product testing

- *Covers both design and production.*
- *A + tests on specific aspects of the product carried out by an in-house accredited body or under the responsibility of a notified body chosen by the manufacturer*:*

A2 - Internal production control + supervised product checks at random intervals

- *Covers both design and production.*
- *A + product checks at random intervals carried out by a notified body or in-house accredited body*.* ***[* The legislator may restrict manufacturer's choice]***

Module B - Description

B - EU-type examination

- ***Covers design.***
- *It is always followed by other modules by which the conformity of the products to the approved EU-type is demonstrated.*
- *A notified body examines the technical design and or the specimen of a type and verifies and attests that it meets the requirements of the directive by issuing an EU-type examination certificate.*
- *There are 3 ways to carry out EU-type examination:*
  - ***1) production type,***
  - ***2) combination of production type and design type and***
  - ***3) design type***

Module C - Description

C - Conformity to EU-type based on internal production control

- *Covers production and follows module B.*
- *The manufacturer ensures the conformity of the products to the approved EU-type*.

C1- Conformity to EU-type based on internal production control plus supervised product testing

- Covers production and follows module B.
- C + tests on specific aspects of the product carried out by an in-house accredited body or under the responsibility of a notified body chosen by the manufacturer*

C2 - Conformity to EU-type based on internal production control plus supervised product checks at random intervals

- Covers production and follows module B.
- C + product checks at random intervals tests on specific aspects of the product carried out by a notified body or in-house accredited body*

Module D - Description

D - Conformity to EU-type based on quality assurance of the production process

- *Covers production and follows module B.*
- *The manufacturer operates a production (manufacturing & inspection of final product) quality assurance system in order to ensure conformity to EU-type.*
- *The notified body assesses the quality system.*

D1 - Quality assurance of the production process

- *Covers both design and production.*
- *The manufacturer operates a production (manufacturing part and inspection of final product) quality assurance system in order to ensure conformity to legislative requirements (no EU-type, used like D without module B).*
- *The notified body assesses the production (manufacturing part and inspection of final product) quality system*

Module E - Description

E - Conformity to EU-type based on product quality assurance

- *Covers production and follows module B.*
- *The manufacturer operates a product quality (=production quality without the manufacturing part) assurance system for final product inspection and testing in order to ensure conformity to EU-type.*
- *A notified body assesses the quality system.*

The idea behind module E is similar to the one under module D: both are based on a quality system and follow module B. Their difference is that the quality system under module E aims to ensure the quality of the final product, while the quality system under module D (and D1 too) aims to ensure the quality of the whole production process (that includes the manufacturing part and the test of final product). E is thus similar to module D without the provisions relating to the manufacturing process.

Module E1 - Description

E1 - Quality assurance of final product inspection and testing

- *Covers both design and production.*
- *The manufacturer operates a product quality (=production quality without the manufacturing part) assurance system for final product inspection and testing in order to ensure conformity to the legislative requirements (no module B (EU-type), used like E without module B).*
- *The notified body assesses the quality system.*

The idea behind module E1 is similar to the one under module D1: both are based on a quality system. Their difference is that the quality system under module E1 aims to ensure the quality of the final product, while the quality system under module D1 aims to ensure the quality of the whole production process (that includes the manufacturing part and the test of final product). E1 is thus similar to module D1 without the provisions relating to the manufacturing process.

Module F - Description

F - Conformity to EU-type based on product verification

- *Covers production and follows module B.*
- *Manufacturer ensures compliance of the products to approved EU-type.*
- *The notified body carries out product examinations (testing of every product or statistical checks) in order to control product conformity to EU-type.*

Module F is like C2 but the notified body carries out more systematic product checks.

F1 - Conformity based on product verification

- *Covers both design and production.*
- *The manufacturer ensures compliance of the manufactured products to the legislative requirements.*
- *The notified body carries out product examinations (testing of every product or statistical checks) in order to control product conformity to the legislative requirements (no EU-type, used like F without module B).*

Module F1 is like A2 but the notified body carries out more detailed product checks.

Module G - Description

G - Conformity based on unit verification

- *Covers both design and production.*
- *The manufacturer ensures compliance of the manufactured products to the legislative requirements.*
- *The notified body verifies every individual product in order to ensure conformity to legislative requirements (no EU-type).*

Module H - Description

H - Conformity based on full quality assurance

- *Covers both design and production.*
- *The manufacturer operates a full quality assurance system in order to ensure conformity to legislative requirements (no EU-type).*
- *The notified body assesses the quality system.*

H1 - Conformity based on full quality assurance plus design examination

- Covers both design and production.
- The manufacturer operates a full quality assurance system in order to ensure conformity to legislative requirements (no EU-type).
- The notified body assesses the quality system and the product design and issues an EU design examination certificate.

Module H1 in comparison to module H provides in addition that the notified body carries out a more detailed examination of the product design

The following procedures are possible

1. **B+C:** EU-type examination (**B**) followed by Conformity to EU-type based on internal production control (**C**)
2. **B+C1**- EU-type examination (**B**) followed by Conformity to EU-type based on internal production control plus supervised product testing (**C1**)
3. **B+C2:** EU-type examination (**B**) followed by Conformity to EU-type based on internal production control plus supervised product checks at random intervals (**C2**)
4. **B+D:** EU-type examination (**B**) followed by Conformity to EU-type based on quality assurance of the production process (**D**)
5. **B+E:** EU-type examination (**B**) followed by Conformity to EU-type based on product quality assurance (**E**)
6. **B+F:** EU-type examination (**B**) followed by Conformity to EU-type based on product verification (**F**)

Conformity assessment modules assigned to various product categories

- Low Voltage Directive: Module **A**
- Toy Safety Directive - HS: Module **A**
- Toy Safety Directive - Non HS: Modules **B & C**
- Machinery Directive -Non Annex IV: **A**
- Machinery Directive - Annex IV + HS: **A** or **B & C** or **H**
- Machinery Directives - Annex IV + Non HS: **B & C** or **H**
- Pressure Equipment - Cat 1: **A**
- Pressure Equipment - Cat 2: **A2** or **D1** or **E1**
- Pressure Equipment - Cat 3: **B+C2** or **B+D** or **B+E: B+F** or **H**
- Pressure Equipment - Cat 4: **B+D** or **B+F** or **G** or **H1**

Toy Safety Directive - 2009/48/EC

- *Article 4 (2)*: Manufacturers shall ……carry out or have carried out the applicable conformity assessment procedure in accordance with Article 19.
- *Article 19 (2):* If the manufacturer has applied harmonised standards, the reference number of which has been published in the *Official Journal of the European Union*, covering all relevant safety requirements for the toy, it shall use the internal production control procedure set out in **Module A** of Annex II to Decision No 768/2008/EC.

Low Voltage Directive 2014/35/EU

- *ANNEX III*
- *MODULE A*
- *Internal production control*
- *1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the electrical equipment concerned satisfy the requirements of this Directive that apply to it.*

Machinery Directive 2006/42/EC

Article 12: Procedures for assessing the conformity of machinery

- Machinery NOT in Annex IV machinery: **Module A.**
- Machinery in Annex IV and manufactured in accordance with the harmonised standards:
  - **Module A**; **or**
  - **Module B & Module C**: **or**
  - **Module H**
- Machinery in Annex IV and has not been manufactured in accordance with the harmonised standards:
  - **Module B & Module C**: **or**
  - **Module H**

Pressure Equipment Directive - 2014/68/EU

The conformity assessment procedures to be applied for the various categories are the following:

- Category I: Module **A**
- Category II: Module **A2**; Module **D1**; Module **E1**
- Category III: Modules **B** (design type) + **D;** Modules **B** (design type) + **F**; Modules **B** (production type) + **E**; Modules **B** (production type) + **C2**; Module **H**
- Category IV: Modules **B** (production type) + **D**; Modules **B** (production type) + **F**; Module **G**; Module **H1**

The different conformity assessment modules - PPE Regulation (EU) 2016/425

PPE Category	Activity	89/686/EEC	(EU) 2016/425
Category I Simple PPE	Placing product on to the market	Manufacturers self declaration	Module A
Category II Intermediate PPE and Category III Complex PPE	Initial product approval	EC type examination Manufacturers self declaration	Module B Module C
Category III Complex PPE only	On-going surveillance through testing	EU-type examination plus supervised product checks at random intervals	Module B Module C2
Category III Complex PPE only	On-going surveillance through factory auditing	EU- type examination plus QA of production process	Module B Module D

Construction Products Regulation (EU) No 305/2011

- **Harmonises**
  - the methods of assessment and test,
  - the means of declaration of product performance; and
  - the system of conformity assessment of construction products, but
- **NOT national building regulations**.
- The choice of required values for the particular intended use is left to the regulators and public / private sector procurers at the national level.
- Products covered by a harmonised European standard (**hEN**) or a European Technical Assessment (**ETA**).

Construction Products Regulation (EU) No 305/2011

- **Assessment and verification of constancy of performance [AVCP]**
- AVCP is the term applied to define the degree of involvement of third parties in assessing the conformity of the product according to the relevant technical specification(s).
- For each product family, the system of AVCP is decided collectively by the Member States and the European Commission.
- They do so on the basis of the implications of the product on health and safety and on the particular nature and production process for the product itself.

C
P
R

System type	Responsibility	Type of notified body	Tasks
System 1+	Notified body	Productcertification body	Initial Inspection of the fpc system Continuous Surveillance of the fpc system Determination of product type Audit testing
	Manufacturer		Factory Production Control and further testing of samples
System 1	Notified body	Product certification body	Initial Inspection of the fpc system Continuous Surveillance of the fpc system Determination of product type
	Manufacturer		Factory Production Control and further testing of samples
System 2+	Notified body	Factory production control certification body	Initial Inspection of the fpc system Continuous Surveillance of the fpc system
	Manufacturer		Factory Production Control and further testing of samples Determination of product type
System 3	Notified body	Test Laboratory	Determination of product type
	Manufacturer		Factory Production Control
System 4	Manufacturer	No independent involvement	Factory Production Control Determination of product type

Conformity assessment

- Conformity assessment is the responsibility of the manufacturer, whether there is involvement of a notified or in-house accredited conformity assessment body, or not.
- Involved in conformity assessment are the legislator, the manufacturer and (if provided for by the legislation) the notified or in-house accredited conformity assessment body.
- The modules used for both the design and the production phase or for each phase **may or may not** involve a notified body.
- In-house accredited conformity assessment bodies must demonstrate the same level of technical competence and impartiality as notified bodies.

Conformity assessment

- In EU harmonisation legislation, conformity assessment procedures cover both design and production phases. They are composed of one or two modules. Some modules cover both phases. In other cases, distinct modules are used for each phase.
- Decision No 768/2008/EC lays down the “horizontal menu” of conformity assessment modules and the ways procedures are built of modules.
- Legislator selects from the menu of conformity assessment modules/procedures the most appropriate ones for the concerned sector.

First option for conformity assessment

- It is established that there is no need for third-party involvement.
- A declaration (accompanied by the relevant technical examinations and documentation) of the manufacturer is enough to ensure the conformity of the product(s) in question against the relevant legislative requirements.
- In this case the manufacturer himself carries out **all** required controls and checks, establishes the technical documentation and ensures the conformity of the production process.

Second option for conformity assessment

- Conformity assessment is performed by an accredited in-house conformity assessment body that is a part of the manufacturer's organisation.
- Must not have any activities other than conformity assessment and must be independent from any commercial, design and production entities.
- Same technical competence and impartiality as external conformity assessment bodies, through accreditation.
- Manufacturers may operate very well equipped testing laboratories and their competence can be higher than the abilities of external bodies.
- For new innovative complex products, the testing know-how remains inside the manufacturers.

Third option for Conformity Assessment

- In some other cases the legislator may consider the intervention of a third party i.e. an external conformity assessment body, necessary.
- Such a body must be impartial and fully independent from the organisation or the product it assesses.
- It cannot engage in any activity that may conflict with its independence and
- It cannot have user or other interests in the product to be assessed.

Conformity Assessment

- The manufacturer or the authorised representative must draw up an Declaration of Conformity
- This should contain all information to identify:
  - the product
  - the legislation according to which it is issued
  - the manufacturer or the authorised representative
  - the notified body if applicable
  - a reference to harmonised standards or other normative documents, where appropriate.

Conformity assessment

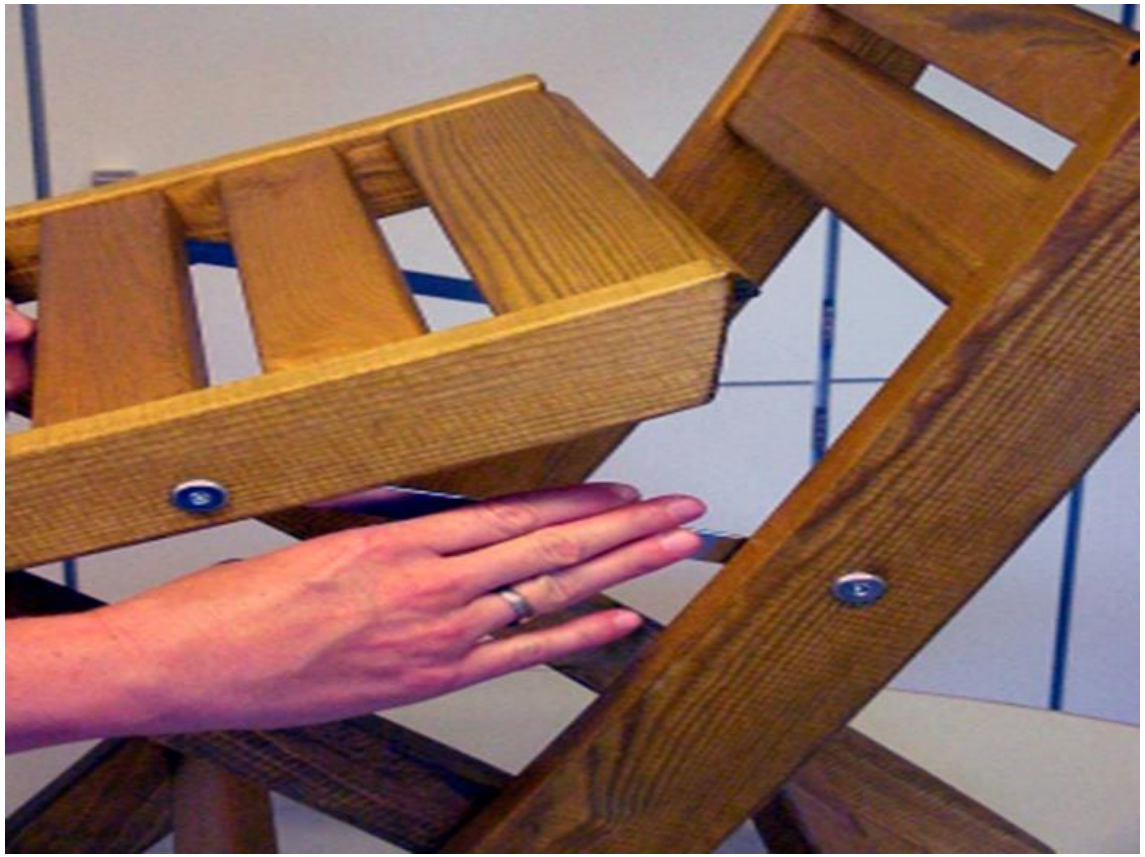
- A **Notified Body** verifies the compliance of a product by conducting a conformity assessment. It also ensures that the technical documentation sufficiently supports product compliance.
- When the Notified Body is convinced of a product's compliance, it issues a ***certificate of conformity*** to confirm this.
- The manufacturer will then draw up the ***Declaration of Conformity*** (**DoC**) to attest on his sole responsibility for conformity to the relevant Directive.
- The establishment of the **DoC** is a legal obligation.

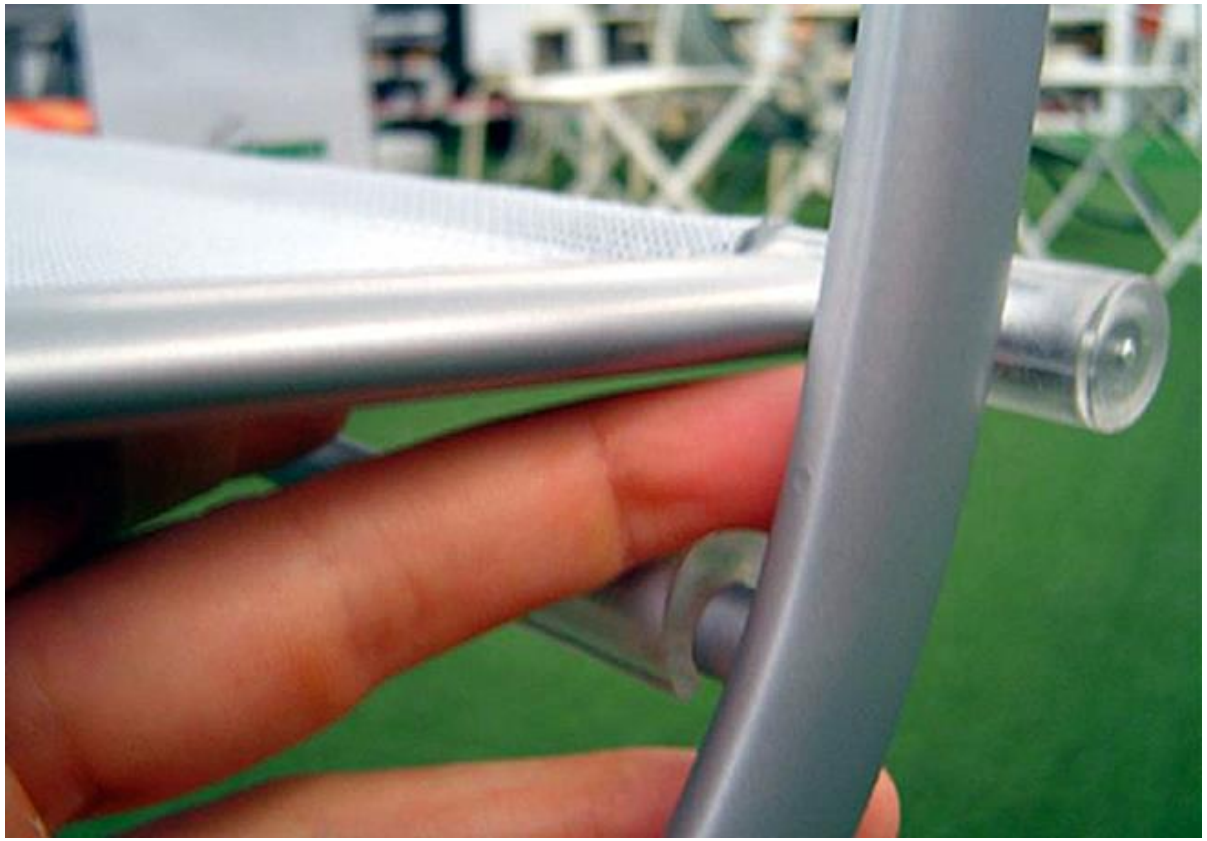
CE marking - General principles

- **CE marking *must*** and ***can only*** be affixed to products for which it is foreseen in legislation
- Affixing CE marking = taking responsibility of conformity
  - Obligation for Member States to protect the marking
  - Ensure correct implementation of the CE marking regime
  - Take action against improper use of CE marking
  - provide deterrent penalties for violations

GPSD - Folding chairs

- HAZARD =Risk of entrapment and crushing of fingers



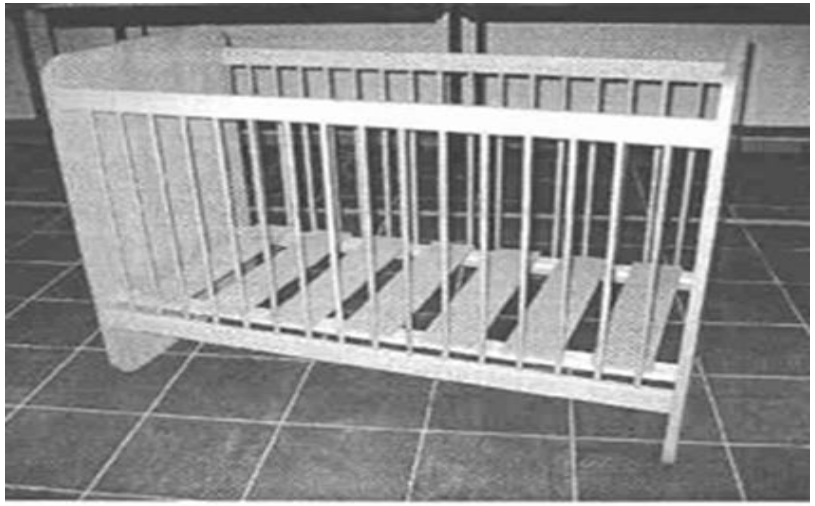


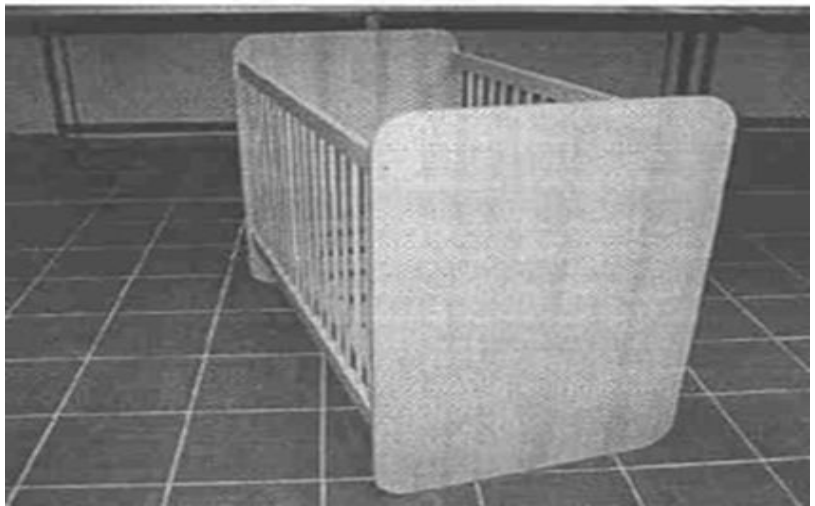
GPSD - Child's Hooded Top

- Hood drawstring can be pulled tight
- Contrary to EN 14682
- Hood cords are banned on outdoor garments if the flat chest measurement is less than 44 cm
- Risk of strangulation
- 23 deaths and 56 non-fatal incidents in 5 years to 2001 [US]

GPSD - Children's cot

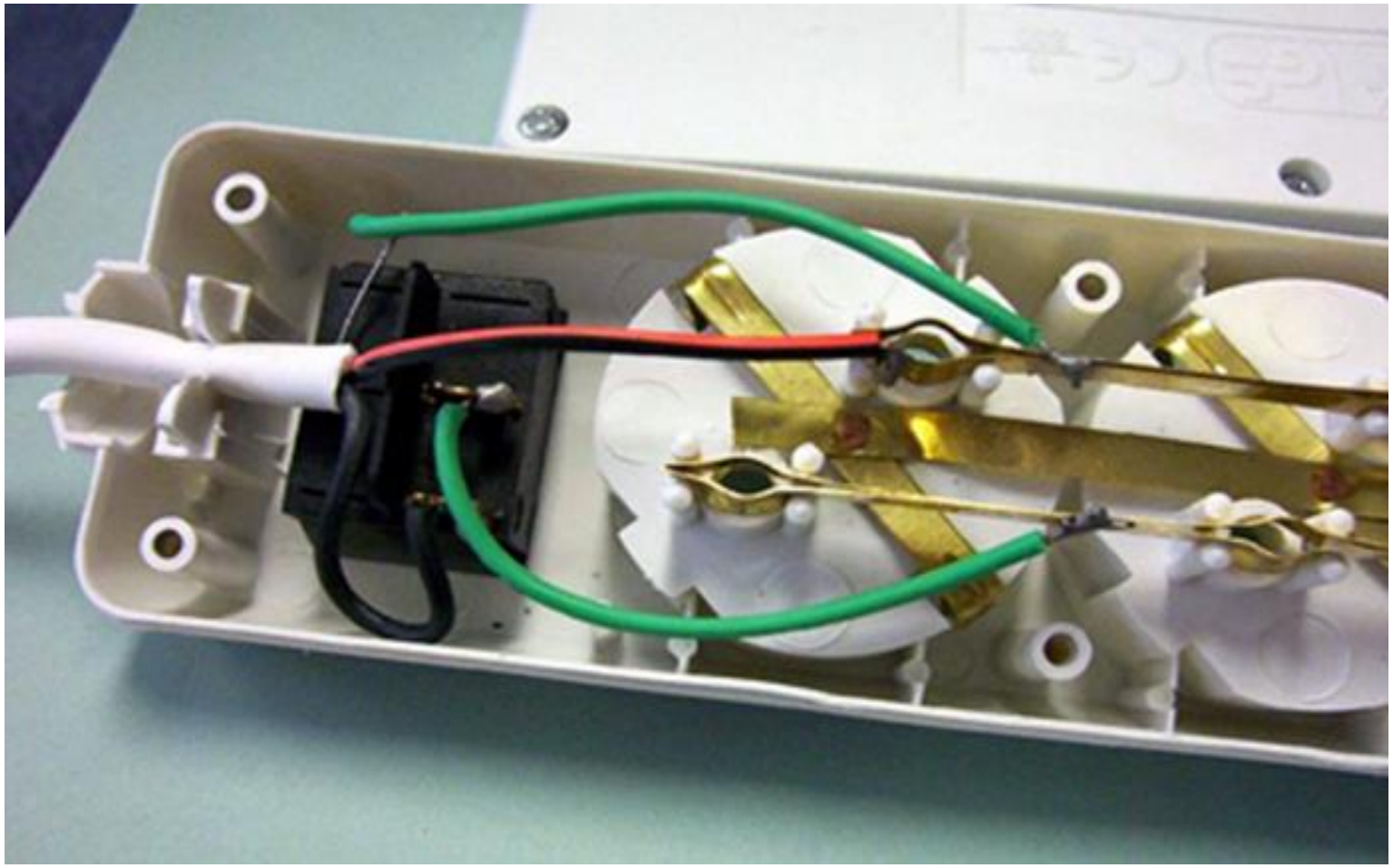
- Excessive distances between the bed base slats and between the vertical bars
- Child can be trapped between the slats or bars
- Children have died through strangulation

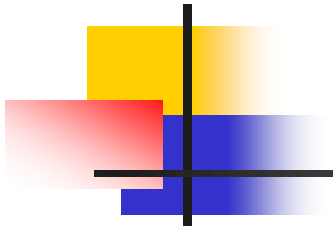




LVD - Extension supply cord

- Only 2 core cable
- Missing earth connection
- Fake safety symbols
- Risk of electric shock





THANK YOU

ANY QUESTIONS?