



# **Supplier's Declaration of Conformity, a challenge for Market Surveillance Authorities ?**

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# The SDoC the key of trust

## SDoC >>>> Supplier's Declaration of Conformity



- With the right key the EU-door will be opened for **PRODUCTS** from third countries
- The industry is responsible for the key

Legal frame work > EU Decision 768/2008/EC



# Programme presentation

1. How to contact the manufacturer?
2. How to check the conformity of products?
3. Cooperation Market surveillance authorities
4. The use of Supplier's Declaration of Conformity
5. Technical documentation
6. Experiences of Market surveillance authorities in the EU
7. European cross border campaigns
8. Experiences with third countries and industry





# How to contact manufacturers?

- **Manufacturers or their representatives**
- **General Risk based approach**
- **In case of**
  - non-compliant(ce) products
- **Action to market surveillance authorities**
  - Safeguard procedure
- **Dangerous products<> withdrawn of the EU market**
  - Informing Commission and Member States
  - RAPEX electronic system
  - To inform the Commission and other Member States



# How to check conformity of products

- **Technical documentation file**
- **The Technical Documentation contains all relevant technical information and tests which must confirm and prove that all the essential requirements set out in the CE certification directives have been met.**

•If not using the route of harmonised standards:

•Opinion notified body in case of not using



# Technical documentation (1)

- **Authorities have legal right to obtain all relevant technical information to check the assessment conformity**
- **Files are strictly for the authorities**
- **Confidentiality of the files**
- **Full cooperation of the manufacturers**
- **10 year period after > last product manufactured**



# Technical documentation (2)

- **Legal basis is mentioned in the Directives**
  - **General description of product**
  - **Conceptual design**
  - **Applicable (harmonised Standard's)**
  - **Results of design calculations**
  - **Test reports**
  - **Updating information**
  - **Information from involved the Notified Body**
  - **For the R&TTE Directive a guide for industry is available**





# Supplier's declaration of conformity

- The compliance of a product with all relevant essential requirements is declared in an “EC” Supplier's Declaration of Conformity (SDoC) issued by the manufacturer
- SDoC is an “official” declaration, it must be signed by a person “empowered to bind the manufacturer or his authorised representative, located in the European Union”.
- The layout of the SDoC can take any form as long as the minimum required relevant information is provided
- The SDoC should conform annex 3 (Dec.768/2008/EC)





# Examples Supplier's Declaration of Conformity

## EC Declaration of Conformity

The following

**Applicant :** GEMBIRD ELECTRONICS LTD  
1102 News Building,  
#2 Shen Nan Zhong Lu, Shenzhen, P.R. China

**Equipment :** Computer parts

**Model Nos. :** PCMCIA-USB24

**Product description :** PCMCIA-USB24 USB 2.0 CardBus PCMCIA card 4  
USB 2.0 ports

We declare under our sole responsibility that the products listed above are in conformity with the Low Voltage Directive 2006/95/EC in order to comply with the requirements in the Council Directive 2006/95/EC relating to electrical equipment designed for use within certain voltage limits and the Amendment Directive 93/68/EEC.

For the safety evaluation the following standards were applied:

EN55022:2006; EN55024:1998+A1:2001+A2:2003; EN61000-3-2:2000+A2:2005; EN61000-3-3:1995+A1:2001+A2:2005;

The following manufacturer/WITHIN Europe is responsible for this declaration:

**GMB Tech (Holland) B.V.**  
Marathon 11, 1213PG Hilversum, The Netherlands  
Tel: +31-35-6038110. Fax: +31-35-6029045

Director



Authorized signature

Hilversum / Oct. 21, 2005  
Place and Date

**Not correct**

## EC-Declaration of Conformity

We, the undersigned,

Company	Hesdo bv
Address, City	Azielaan 12, 's-Hertogenbosch
Country	The Netherlands

declare that the following equipment:

Product description / Intended use	Portable MP-3 speaker / amplifier
Name / model	Alecto WSP-47
EU / EFTA member states Intended for use	EU: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Hungary, Germany, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, United Kingdom EFTA: Switzerland, Iceland, Liechtenstein, Norway

is in conformity with the following relevant harmonised standards:

EN 55013 : 2001 + A1 : 2003  
EN 55020 : 2002 + A1 : 2003 + A2 : 2005

Following the essential requirements and provisions of the EMC Directive 89/336/EEC as amended by Directives 92/13/EEC and 93/68/EEC



Drawn up in	's-Hertogenbosch
Date	June 1, 2006

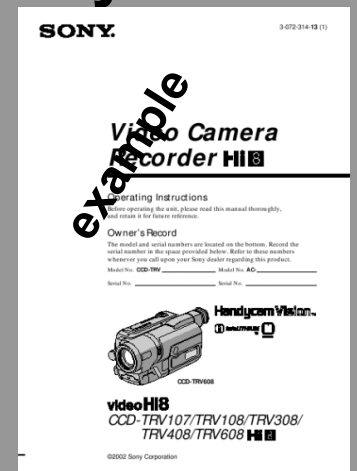
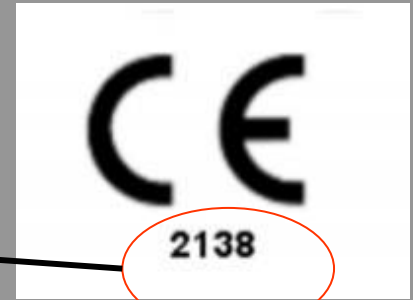
A copy of this declaration can be obtained by a written request to:

Hesdo bv  
Azielaan 12  
5232 BA 's-Hertogenbosch  
The Netherlands



# Administrative check

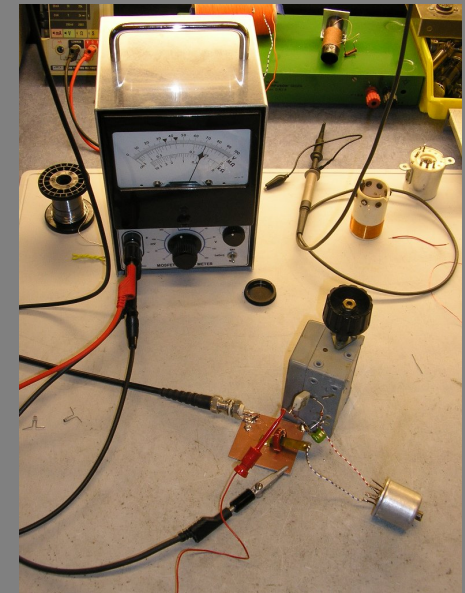
- CE marking
- Type, serial number etc
- Number notified body if applicable
- User information
- Correct Supplier's Declaration of conformity
- Used harmonised standards
- Declaration manufacturer
- For industry a checklist
  - can be find on the EC website



# Essential requirements

- **Checking the essential requirements**

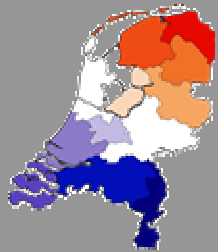
- **Measurements**
- **Accredited laborator(i)es by**
- **Or by the MS authorities**
- **Using Suppliers' DoC**
- **Used Harmonised standards**
- **Technical documentation**





# EU market surveillance products

- 27 market national surveillance authorities' responsibility in the EU



The Netherlands

**Member States are responsible for the EU**

**25 % products are passing through the harbour of Rotterdam**



# Cooperation Market surveillance authorities

- **Market surveillance is an EU matter**
- **Cooperation between these authorities**
- **27 members, included**
  - **Switzerland, Norway and Iceland**
- **Administrative Cooperation, called ADCO**
- **Different ADCO's (ADCO/LVD. ADCO/EMC etc.)**
- **Cross border campaigns**
- **Electronic system of exchange of information**
- **Exchange national programmes**



# European cross border campaigns

- **MSA >>> cross border MS campaigns**
- **Results non-compliance of mass products**
  - **Radio Short range devices > 80 %**
  - **Electrical tools lower than > 72 %**
  - **Low power FM transmitters > 42 %**
- **Most non-compliant (ce) equipment come from third countries (China, Korea)**





## **Experiences with third countries and industry**

- **Some mass products from third countries are not traceable**
- **High level of non compliance of mass products**
- **General no EC marking**
- **Name of manufacturer is missing**
- **Not willing to deliver the technical file construction**
- **Different importers in the EU**
  - **who is responsible for placing on the EU market?**
  - **Importers are informed about EU regulations**



**Thanks for your attention**

**Questions ?**



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