Disclaimer

* This presentation has nothing to with my current employer and its internal practices
* I will try to avoid sharing names and internal practices of my previous companies during my presentations (unless they no longer exist)
  * All of the companies I worked for or with were successful companies in their respective fields
You all are familiar with CE marking
  * EMC
  * Safety
  * Machinery
  * IVD, MDD, etc...

Now RoHS 2 is a CE marking directive
  * Requirements are fairly different
EU is comprised of 28 EU member countries

* There are several countries those are not the member but comply with EU requirements e.g. Turkey

**Legislative acts:**

* **Proclamation:**
  * A formal announcement made by the crown e.g. Declaration of War, State Emergency etc.

* **Regulation:**
  * Directly applicable in all member states without the need for legislation in the nation

* **Directive:**
  * Are not self-executing. The member states are left with leeway to decide which rules are to be adopted
  * Directives, unlike regulations, need to be transposed into national laws before adoption in principle.
Product Groups Affected by CE Marking Directives

- Active implantable medical devices
- Appliances burning gaseous fuels
- Cableway installations designed to carry persons
- Eco-design of energy related products
- **Electromagnetic compatibility**
- Equipment and protective systems intended for use potentially explosive atmospheres
- Explosives for civil uses
- Hot-water boilers
- **In vitro diagnostic medical devices**
- Lifts
- **Low voltage**
- Machinery

- Measuring Instruments
- **Medical devices**
- Noise emission in the environment
- Non-automatic weighing instruments
- Personal protective equipment
- Pressure equipment
- Pyrotechnics
- Radio and telecommunications terminal equipment
- Recreational craft
- Safety of toys
- Simple pressure vessels
- **Restriction of the use of certain hazardous substances RoHS 2**
RoHS: EU Directive 2011/65/EU

- Free download using Yahoo or Google search function
- The directive references CE marking as per
  - EU decision 768/2008, Annex II, Module A
    - But that was not clear enough
  - EN50581 guidance document was released to clarify Technical Files requirements related to RoHS directive 2011/65/EU
Who can request for Technical File?

* Regulatory Authority – also known as Competent Authority (CA)
  * In member country has this government agency responsible for transposition of directive into national laws and enforcement
* Port of Entry - customs
* Customer
  * Legally our customer (Importer) e.g. dealer, distributor, retailer, is responsible to place (buy) compliant products
Steps for Technical File for RoHS

* It can be a separate Technical file for RoHS compliance purposes, or
* Can be made a part of the existing technical file
My professional recommendation is to keep it separate:

- RoHS directive does not require audit by notified bodies
  - It is regulated/enforced by the Competent Authorities (CA) of the respective member countries
- You do not want to include notified bodies when they come to audit for other CE marking directive compliance audit
  - Scope would be humongous
Technical file key requirements

* Declaration of Conformity
* General Description of the product
* Controls related to RoHS
  * Brief Description with reference procedures
    * Engineering, Procurement, Incoming, Production, Shipping, Field Service (Repair and Refurbishing), Auditing, Corrective and Preventive actions related to non-compliance (notification, recall, corrections, stop ship etc.)
* Compliance Assessment procedure
  * Based on parts assessments, testing, audits, procedures, repositories
EC Declaration of Conformity

1. No ... (unique identification of the product):

2. Name and address of the manufacturer or his authorized representative:

3. This declaration of conformity is issued under the sole responsibility of the manufacturer (or installer):

4. Object of the declaration (identification of product allowing traceability. It may include a photograph, where appropriate):

5. The object of the declaration described above is in conformity with the relevant Community harmonization legislation: ......................

6. References to the relevant harmonised standards used or references to the specifications in relation to which conformity is declared:

7. Where applicable, the notified body ... (name, number) ... performed ... (description of intervention) ... and issued the certificate: ...

8. Additional information:

Signed for and on behalf of: ......................................................

(place and date of issue):

(name, function) (signature):
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Compliance Assessment

- Objective evidence of RoHS compliance of every part that is
  - Integral and essential part of the system
    - Electrical, Electronic, Mechanical, Plastics, Cables, Labels, Paint, Ink, ... etc.
  - Recommended Objective evidences:
    - Certificate of compliance from the Manufacturer (Minimum Required)
      - Letter Head, signatures, date, exemptions, etc.
    - Materials Declaration (e.g. concentration of all RoHS substances; High Level or at Homogenous Level
      - Industry is heading for full declaration
    - Test/Analytical Data
  - Most Importantly declaration should be trustworthy
    - You are responsible as the producer: Consider audits, Testing
EN50581

Proposed Title:
Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
Figure 1 — Process followed by the manufacturer to create the technical documentation
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- Compliance Assessment procedure
  - Based on parts assessments, testing, audits, procedures, repositories

Now you can apply CE Marking on your product
Additional Comments

* Technical file is required from the enforcement date
  * It is OK to have it ready as soon as possible but legally required on or after the enforcement date
  * You can ship a RoHS compliant product before the enforcement date
    * But there is no legal requirement for Technical file
* It must be retained for a minimum of 10 years
  * From the date product is placed on the market
Additional Comments

* CE stands for
  * Communauté Européenne (European Community)
  * Conformité Européenne (European Conformity)
  * CE Marking is like an passport symbol of free marketability in the EU member countries
    * Product must be compliant to fully or partially of the all directive as applicable
Questions