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Choose certainty.
Add value.

Providing peace of mind that products are
safe, reliable and compliant.



- First introduced in 1973 as 73/23/EEC (The LVD)
- Amended in 1993 by 93/68/EEC
 - (The CE Marking Directive)
- Current edition is 2006/95/EC (Codified version)
 - (generally tidied up and brought into line with the New Approach Conformity Assessment Procedures 93/465/EEC)
- New edition is 2014/35/EC and comes into force 20th April 2016 and is in line with the New Legal Framework 768/2008/EC (NLF)

- LVD is simplest of the directives - one conformity assessment module
- Requirements are laid out in **Article 3**
- “Electrical Equipment may be made available on the Union market only if, having been constructed in accordance with good engineering practice in safety matters in force in the Union, it does not endanger the health and safety of persons and domestic animals, or property, when installed and maintained and used in applications for which it was made.”
- **Annex I** Lists the principal elements of the safety objectives which include safety marking, that it can be safely assembled and connected, protects persons and domestic animals from harm, temperatures, arcs or radiation and other non-electrical dangers
- That the insulation is suitable for **Foreseeable** conditions

Foreseeable crops up several times

- It is in Whereas Clause 25: where it talks about conditions of use that can be **reasonably foreseen**, when such use could result from **lawful and readily predicable human behaviour**
- It is in Annex 1: 2(d) when it talks about insulation
- Annex 1: 3(c) refers to foreseeable conditions of overload
- However, this does not include deliberate misuse
- if a product is not unreasonably dangerous when used for a purpose and in a manner that is reasonably foreseeable, it simply is not defective, and the manufacturer will not be liable



- The New Legislative Framework labours long on the “Risk” that a product may provide to the user and their domestic animals
- The LVD does the same and this is the first obligation on a manufacturer in Annex III which describes Module A, Internal Production Control that a manufacturer should use to establish conformance of their product:
- “The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the electrical equipment’s conformity to the relevant requirements, **and shall include an adequate analysis and assessment of the risk(s).** The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the electrical equipment...etc...”

Foreseeable Risks?



Product Service

- So we have a requirement for a manufacturer to protect the user against reasonably foreseeable risks resulting from their lawful and readily predictable behaviour
- However, this does not include unreasonable behaviour
- A manufacturer can protect themselves by documenting their design, applying Harmonized Standards, keeping the results of calculations, examinations performed and any test reports. They must take all measures necessary during manufacturing to ensure compliance. They must correctly mark and label the product and draw up a Declaration of Conformity – All detailed in Annex III

So what happens?



Product Service

- A manufacturer will often apply a Harmonised Standard.
- For a lot of electrical equipment this is EN60950-1, EN60065 or EN60335 series but recently IEC62368-1 a “Hazard-Based” safety standard has become available for IT equipment
- ECMA International make available a useful comparison Technical Report **TR/106** that compares the two principle IT safety standards EN60950-1 and IEC62368-1
- Manufacturers will normally engage a test house for determining the compliance of their products to the various directives

So what happens?



Product Service

- Test houses normally apply a Standard to an accredited test schedule, this cannot include all operational modes, only those declared by the manufacturer
- A test house works to contract so if they are not told specifically to do something they normally will not do it
- Can a manufacturer presume that their product is safe if it passes the test standard? – No
- The Standard may be imperfect, the hazard may not be included in The Standard, all operational modes may not be tested, a limited number of tests and samples are available for inspection, the product may contain innovative features not included in The Standard

Is this a change to the LVD?



Product Service

- Is this a change to the Directive and Standards or a change in emphasis in what is already required?
- Well most people will say it is a new obligation but my view is that it is already required as an act of due diligence required of all manufacturers
- This has always been inherent in the work that test houses and manufacturers should have been doing

Examples:

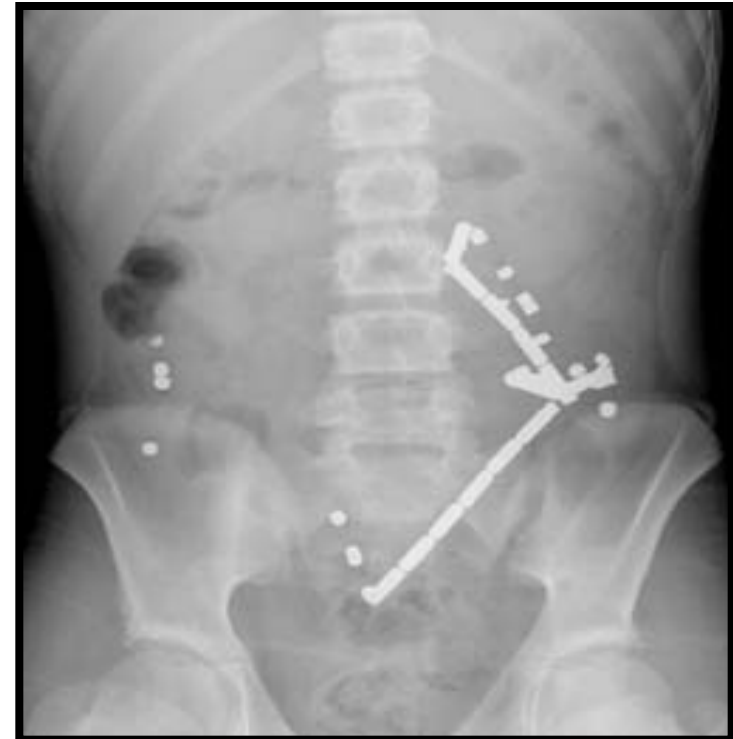
- Waterproof watches, Famous case of due-diligence
- Caps on USB memory sticks!
- Coin cell batteries
- Flammability of TV cases
- Super Magnets in toys

Example - Magnets



Product Service

New Technology Toys made from Neodymium magnets – hazard not assessed



**9 million toys recalled; 33 serious injuries – 2 deaths;
12 yr old swallowed 28 magnets**

Example – Coin Cell Batteries



Product Service

- A 2-year-old Arizona boy undergo 18 surgeries in the past year because he swallowed a nickel-sized battery
- No one saw the child swallow the remote control battery, but he soon had cold-like symptoms. When he finally had a X-ray, the battery had already started to burn through his oesophagus. The boy had the battery inside him for about three days.
- One of his nurses said this type of incident is not uncommon. "We have had two similar cases in the past couple weeks, and it's becoming more and more frequent."





- Test Houses work to Harmonized Standards and Accredited Test Schedules - their tests may not cover a hazard if it is not part of the Applied Standard or if you do not declare that operation mode
- Because it passes a Harmonized Standard it does not mean the product is safe but there is a presumption of conformity
- The Manufacturer is ultimately responsible for their own product - **IEC Guide 116** covers Risk Estimation very well
- This is not specifically a change to the Directive or the Standard – it is a clarification of what is already there
- It is likely to make manufacturers, and test houses more conservative and more risk adverse

Thank you for listening!

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