COCIR Position Paper
Overlap between Medical Device Directive (MDD) and Machinery Directive (MD)

The amendment of the Medical Device Directive 93/42/EEC by the Directive 2007/47/EC introduces in article 3 additional requirements for medical devices that are also machinery.

> *Article 3 – Essential requirements*
> *The device must meet the essential requirements set out in Annex I which apply to them, taking into account of the intended purpose of the device concerned. Where the relevant hazard exists, devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EEC must also meet the essential health and safety requirements set out in Annex I of that Directive to the extent to which those essential health and safety requirements are more specific than the essential requirements set out in Annex I of this Directive.*

According to this article 3, only some essential requirements from the Machinery Directive (MD) will apply. Other parts of the MD will not apply, nor will the related conformity assessment procedure. COCIR has identified potential conflict areas; see the non-exhaustive list of examples in the Annex.

COCIR recommends that a MDEG Working Group should be established to identify those situations for specific devices. This working group must come to practical recommendations to be published in the form of European guidelines (MEDDEV) for use by manufacturers. These recommendations should also be used as input for amending, as needed, the medical device standards.

COCIR is ready to contribute to this work by bringing in the technical expertise of its members.

When the amended MDD enters into force by March 2010, until such MEDDEV has been prepared, COCIR recommends that the following rules apply:

- The Risk Management described in EN 14971 prevails over the Machinery Directive approach. This Risk Management standard, harmonized under MDD, has been specifically developed for medical devices and explicitly takes into account the risk / benefit ratio.
- Standards harmonised under the MDD prevail over general rules of the Machinery Directive.
- The essential requirements of the MD apply only when the related hazard is not identified in the essential requirements of the MDD or in the harmonized standards of the MDD.

Annex

Examples of potential problems in applying the Machinery Directive to Medical Devices

1. The Machinery Directive requirements on safety factor for mechanical strength are different than those specified in the harmonized standards for the MDD. Applying the values from the Machinery Directive would conflict with the medical function and the safety of the patient.

2. Specific requirements in MD on the content of the user instruction:
   - Declaration of Conformity
   - Level of emitted noise
   - References of spare parts
   - Test report for lifting machine
   - Max load and material visible on labels

3. Requirements in MD for supplying specific accessories for maintenance may cause safety concern if the specific accessories are used by unqualified personnel

4. Requirements in MD or specific tests:
   - Noise emission (potential conflict with MRI requirements), vibration
   - Static and dynamic test to be performed on all lifting machine ready to be put on the market

5. Explicit requirements in MD for protective measures may cause conflict with standards EN60601-1 ("Medical Electrical Equipment - Part 1 -General Requirements for Safety") and EN60601-2-32 ("Medical Electrical Equipment – Part 2-32 - Particular requirements for the safety of associated equipment of X-ray equipment") for moving parts and multiple control positions