



**COCIR position**  
**Overlapping Machinery Directive (2006/42/EC) and Medical**  
**Devices Directive (revised 93/42/EEC)**

The revised text of the directive 93/42/EEC introduces in article 3, additional requirements for medical devices that are also machinery.

*Article 3 - Essential requirements*

*The devices must meet the essential requirements set out in Annex I which apply to them, taking account of the intended purpose of the devices concerned. Where the relevant hazard exists, devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC 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.*

There may be complications and conflicting situations when a medical device itself may be safe according to the harmonized standards related to the MDD, but where there is no direct link between these harmonized standards and the essential requirements of the Machinery Directive to demonstrate that the medical device meets the essential requirements of that directive.

From a different perspective, the harmonized standards related to the Machinery Directive have not been developed for use with medical devices, so it may be inappropriate to use them to demonstrate safety and performance of medical devices.

In order to avoid potential conflicts in the application of the directives, COCIR promotes a solution based on the consensus standards that should be developed and harmonized under both directives. A gap analysis should be done for the harmonized standards under the Machinery Directive and those under the Medical Devices Directive in order to identify those advanced safety measures for Machinery Directive that are considered as essential for further risk mitigation of the medical devices. The technical committees most involved in the related standards field should do this gap analysis, the result of which should be used to close the gap by adding to or amending the safety standards, harmonized under the Medical devices directive.

These identified risk mitigation measures would immediately contribute to the state-of-the-art and are to be taken into account in the risk management process. Then the medical devices might be exempted from the Machinery Directive, without any impact on the health and safety while avoiding any overlapping between both directives.

In the case where none of these options is ready before the mandatory application of the revised medical devices directive, practical solutions should be proposed in European guidelines (MEDDEV) to explain which essential requirements from the Machinery Directive should be applied to medical devices, and what type of evidences are expected for demonstrating the conformity of the devices with these essential requirements.

COCIR is ready to contribute to the preparation of these guidelines by bringing the technical expertise of its members.