COCIR Preliminary Position Paper
on the Medical Device Directives (MDDs) revision
to the attention of MDEG members

COCIR represents the European Medical Diagnostic and Imaging, Electromedical and Healthcare IT Industry. Our Industry has always supported strong and effective regulation in its sector and has always taken a very active role supporting the harmonized development of regulations at national, European and global level. This position paper is COCIR’s contribution to the on-going discussions on the MDDs revision and will be updated/revised as discussions progress.

COCIR supports a smart regulation that makes an efficient and effective use of existing resources with an EU-wide regulatory approach with same implementation across all 27 Member States.

This position paper outlines preliminary COCIR proposals for such renewed legislative framework for MDDs in two chapters: A. on the framework governance and B. on selected operational elements.

A. New EU regulatory framework - Governance model

A.1. Nature of legal act
Transform the current EU directives into an EU regulation for better harmonization in the implementation. Continue to use the “New Approach” model and keep what works well.

A.2. Central administration
Centralize administrative functions that support implementation, such as device registration, manufacturer listing, vigilance reporting, EUDAMED, UDI, and clinical investigations.

A.3. Role of EU Member States
Establish a Coordinating Committee of Member States to align implementation. Appropriate consultation with all relevant stakeholders should be part of the process.

A.4. Oversight of Notified Bodies
Mandatory peer oversight of Notified Bodies by Member States should improve quality and consistency of NB-MED operation.

A.5. European guidance and transition period
Review and revise existing guidances during the legislative process “as we go”, and grant fair transition period to all involved stakeholders.

B. New EU regulatory framework - Operational elements

B.1. Components, parts and spare parts
A Generic extension of the regulatory coverage to components, parts and spare parts needs substantial further consideration.

B.2. Conflicting directives
Include all requirements for medical devices in the MDDs and thus prevent conflicting requirements from multiple applicable regulations.

B.3. Medical software
Update the classification rules (Annex IX) to address specific aspects for standalone software.

B.4. International Standards
Adopt as harmonised EN standards identical copies of International Standards.
A. New EU Regulatory framework – Governance model

A.1. Nature of legal act
The current Directive 93/42/EEC (MDD) has been transposed by the Member States into their national legislation. Most of the content of the MDD has been transposed consistently, however some differences in the interpretation and implementation have been observed, in particular:

- Notification of placing on the market of class II and III devices and related information to be provided to the competent authority
- Authorization for Clinical Investigation
- Qualification of the medical software
- Timing for reporting incidents

In some cases, MEDDEVs have been developed to address the difference of interpretation and implementation, however those guidelines are not legally binding.

Transforming the current directive into a regulation ensures an identical transposition of the EU legal act in the 27 Member States and improves the harmonization in its application.

This change in the nature of the legal act must not imply a departure from the “New Approach” model or other fundamental changes.

The current assessment procedures based on the “New Approach” model must be maintained and the MDD revision must not cause any disruption in the current technical content.

A.2. Central administration
COCIR considers the patchwork of administrative procedures across 27 EU Member States, with which manufacturers have to comply in each individual Member State, as quite burdensome and not contributing to the health and safety of the European citizen. COCIR would like to see the principle of “reported once, known everywhere” applied with respect only to several administrative reporting obligations of industry and not technical / scientific registration, such as:

- Device registration
- Manufacturer listing
- Vigilance reporting
- EUDAMED
- UDI
- Clinical investigation notification

This administrative centralization has to be supported by suitable IT-tools, either an extended version of EUDAMED, or a newly designed and more elaborate IT-tool, with access to the collected data for all relevant parties.

A.3. Role of EU Member States
COCIR’s main issue is the different interpretation of the current legal provisions across 27 EU Member States. COCIR calls for greater consistency in interpretation and implementation and improvement of decision making between Member States.

COCIR would like to see the establishment of a Coordinating Committee of Member States, in charge of the tasks of ensuring harmonisation and consistency, and managing relevant actions of Member States. This Coordinating Committee should have a statutory basis and should work in direct relation with the Comitology Committee, which is based on the Treaty (the current Committee based on Art 7 of the MDD). This Coordinating Committee should also have a proper process for consultation of relevant stakeholders in place.
A.4. Oversight of Notified Bodies

In the context of the New Approach, reconfirmed in 2008 as the New Legal Framework, Notified Bodies play a crucial role in the functioning of the European regulatory concept. This role exists in many product sectors, not just for medical devices. Notified Bodies are commercially operating organisations that, under the supervision of their notifying Competent Authority, inspect manufacturers with respect to the evidence of compliance with the European regulatory requirements.

This decentralized approach allows the manufacturer which Notified Body they want to contract with on the basis of competence, language skills, availability, etc., and has proven highly successful. Recently, the European regulatory framework design and in particular the operational context of the Notified Bodies has received some criticism. Although not all of this criticism can be justified, there is room for improvement with a focus on consistent operation, better competence description, and transparency.

As a first step, national guidance and interpretations should be abandoned. Only European guidances and interpretations should be generated and utilized, in line with the COCIR position on the Role of EU Member States; see section A.3.

In the opinion of COCIR, the prime responsibility for the Notified Body functioning must remain with the European Member States, yet without the present exclusivity for the notifying Competent Authority. A scheme of mandatory “peer audits” must therefore be set up in which all EU Member States must participate and that provides for a certain level of random assignment of co-assessing Member State. The outcomes of the joint assessment must, in case of observed lack of adequate performance by the Notified Body, have consequences for that Notified Body that, eventually, could include full withdrawal of its notification.

A.5. European guidance and transition period

COCIR wishes to emphasize that ample time is needed for the transition from the present “MDD/AIMDD/IVD” to the “new EU Regulations” to allow manufacturers to implement the new rules, that is: to adjust products and compliance evidence.

The European legislative text for medical devices, the MDD (and AIMDD and IVDD) is “surrounded” by a cloud of additional guidances for manufacturers, Notified Bodies, as well as for Member States. Those guidances included MEDDEVs, COM decisions, Borderline and Classification guide, informative “Fiches”, NB-MED recommendations, NBOG manuals, etc., and is important for proper and smooth implementation.

The revision of the MDD will likely bring substantive changes in several dimensions. It is therefore crucial that all of the present guidances are critically reviewed and, where relevant, converted into the new context. This process of review and revise should be done –together with key stakeholders- alongside the discussions on the legislative part before that is final: if practical considerations surface during that process, they might be taken on board in time within the legislative process.

Nevertheless, it will be unavoidable to develop guidances after the publication of the legal text of the revised MDD. Also, since the revised MDD will continue to be within the context of the New Legislative Framework, the standards that are presently harmonized under the MDD may all need to be reconsidered for harmonization under the new MDD. As it can be expected that the Annex I, Essential Requirements, will change substantially, as well as possibly the scope of the MDD, substantive changes may be needed in these harmonized standards.
B. New EU Regulatory framework – Operational elements

B.1. Components, parts and spare parts

**Background:** It has been suggested that components, parts and spare parts used in or with medical devices should be subject to the requirements of the MDD.

**COCIR position:** For the original manufacturer of a medical device, components, parts and spare parts are already covered by conformity assessment of the medical device and therefore covered by the CE-mark of the medical device. A generic extension of the regulatory coverage to components, parts and spare parts needs substantial further consideration: it will substantially increase the administrative burden for original manufacturers; it will cause increase of cost with original supply and maintenance, and hence create an even greater demand for non-original supply without bringing any obvious benefit from a safety and quality standpoint.

**Detailed consideration:** For maintenance, repair, upgrades and other purposes, the owner of medical equipment may choose for replacement parts those that are not supplied by the “original” manufacturer. The quality of these components may be such that patients are at increased risk. Such a situation will not occur when components, parts or spare parts from the original manufacturer are used as these are covered under the same quality management system as the main medical equipment.

Expanding the scope of the MDD down to the level of components, parts or spare parts will not only require developing definitions for these elements, but also defining their status as they cannot be considered medical devices in their own right, nor can they be considered accessories to a medical device. That implies a whole new class of products within the medical devices area for which neither the present classification rules apply, nor the available conformity assessment schemes. Worse, for these products, no MDD-harmonized standards will –in general- be available.

However, if a party other than the original manufacturer and without his involvement wishes to place products on the market that may serve as components, parts or spare parts for medical equipment of that original manufacturer, then that party must be able to demonstrate that the component, part or spare part does not negatively impact the safety or performance of the medical equipment.

B.2. Conflicting directives

**Background:** Several Directives apply to the medical devices in addition to the MDD. Those directives may introduce requirements that may conflict or duplicate requirements already addressed in the MDD and as a consequence, the placing on the market of a CE marked device may be hampered or delayed.

**COCIR position:** COCIR suggests to clarify the rules for the joint application of the European directives to medical devices and to include the requirements of those directives in the MDD whenever possible.
Detailed consideration: The conflicts may appear when Directives introduce technical requirements addressing risks already covered by the MDD or when those directives introduce conformity assessment or approval procedures overlapping the conformity assessment procedure of the MDD.

- Other Directives providing for CE marking may include Essential Requirements similar or already covered by the MDD. This was the case for example with the EMC directive (2004/108/EC) and with the Machinery Directive (2006/42/EC).
  
  The solution to avoid conflicts is to incorporate the relevant Essential Requirements in the Annex of the MDD related to the Essential Requirements. This has been done for EMC Directive and will be done for the Machinery Directive in the next MDD revision.

- The same approach should be engaged with the RoHS directive (2011/65/EC) which includes requirement on substances restrictions similar to the Chemical requirements in the MDD. This would avoid duplicating the Conformity assessment procedures.

  The requirements of the other Directives on environment (WEEE and EcoDesign) should also be incorporated in the MDD revision.

- The Directive 97/43/Euratom includes specific requirements on medical devices using ionising radiation, like acceptance testing and device for displaying the dose that should come more in addition to the essential requirements of the MDD. Some cases may occur where a legally CE-marked device does not comply with the requirements of 97/43/Euratom.

  COCIR proposes to include all requirements related to the radiation protection of medical devices in the MDD.

- The revision of the Euratom BSS, that will include the further 97/43/Euratom, will introduce a new procedure for approving new devices before their first placing on the market. This procedure is overlapping the current procedure of notification before the first placing on the market specified in the MDD.

  COCIR propose that EU Commission Directorates involved in the revision of MDD and Euratom BSS agree on a single procedure to be included in the MDD.

- The Directive EMF 2004/40/EC specifies limits for exposure of workers to Electromagnetic Fields, that conflict with the essential requirements of MDD related to non-ionising radiation. Harmonized standards exist that already cover the risks associated with exposure to EMF emitted by MRI (EN60601-2-33). Compliance to these standards shall ensure an adequate protection of the patient and the users and shall justify the exemption of MRI from 2004/40/EC.

B.3. Medical software

Background: It is unclear how the classification rules must be applied to stand alone software products. This creates differences of interpretation and results in discrimination at tender level.

COCIR position: COCIR suggests adapting the existing classification rules, originally developed for Hardware or Hardware/Software combinations, to the specifics of stand alone software a slight adjustment of the existing rules would solve this issue.

Detailed consideration: Stand alone software - if put into a healthcare context by its intended use - is to be considered an active medical device; hence the applicable rules have to be chosen from rules 9-12. The number of applicable rules can be reduced by applying Implementing Rule 2.3 which states that stand-alone software that drives or influences the use of a device, falls automatically in the same class. A further selection of applicable rules can be achieved when taking into account that stand alone software cannot administer or exchange energy (Rule 9), cannot supply energy to be absorbed by the human body (Rule 10), cannot emit ionizing radiation (Rule 10), and cannot administer and/or remove medicines, body liquids or other substances (Rule 11). Hence a statement shall be added to the listed clauses of rules 9, 10 and 11 which explicitly excludes them from application to stand alone software. This would add clarity and fairness across the EU while not changing the regulatory environment.

Further clarification is required on how to interpret “direct diagnosis” and on whether stand alone software could be considered Class I-measuring, while some stakeholders argue that software can only calculate.
B.4. International Standards

Background: One of the pillars of the New Approach is the use of harmonized European Standards to provide “presumption of conformity” with Essential Requirements. To achieve harmonized technical requirements around the world and, hence, to reduce trade barriers, European Standards intended to support the MDD and its Essential Requirements, should be identical to International Standards that reflect the global knowledge of safety and performance experts. The current developments in the EU can be perceived as counterproductive and possibly resulting technical barriers to trade would conflict with WTO obligations of the EU.

COCIR position: International Standards, reflecting international consensus on safety and performance, are the preferred means to demonstrate the safety and effectiveness of medical devices to be placed on the European market. These standards, published as European (or national) standards, should be identical to these international standards, and should be adopted to provide presumption of conformity with the Essential Requirements of the MDD.

Detailed consideration: Where in the present discussions it is perceived that the requirements in the European standards, identical in their requirements to international standards, might show a slight mismatch to the current Essential Requirements, i.e., supposedly not fully cover certain presently applicable Essential Requirements, COCIR considers that this would call to:

- Reconsider the involved Essential Requirements in the MDD revision process,
- Improve the European participation in the international standards development process
- Specifically support and instruct European participants in international standards development, and
- Only as a last resort consider European modifications to international standards.