EMIG wants amending Art. 19, §3 of revised New Approach regulation

COM(2007) 53 final (Proposal for a Decision of the European Parliament and of the Council on a common framework for the marketing of products) – Chapter 4: "Notification of conformity assessment bodies", Article 19 "Notifying authorities" states in paragraph 3:

> "Where the notifying authority delegates, subcontracts or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, the delegated, subcontracted or otherwise entrusted body shall be a legal entity and shall have arrangements to cover liabilities arising from its activities."

While the option of entrusting elements of the process of conformity assessment to non-governmental entities as specified in this paragraph may be fully acceptable or even in the interest of other industry sectors, it will have a major negative impact on the EU's medical device industry in view of worldwide market access.

Why does EMIG believe this ?

In all countries worldwide with an established mature regulatory system for medical device manufacturers **either direct control is exerted by National Authorities or Conformity Assessment Bodies (CABs) are assigned and monitored by the National Authority**. Entrusting non-governmental entities in EU member states will be in contradiction with the emphasis put in countries like e.g. the USA, Canada, Australia/New Zealand and Japan on the high level of quality, safety and performance for medical devices.

Even the possibility for this delegation or subcontracting by EU member states would create serious disadvantages for European Medical Device Manufacturers:

- Loss of credibility in the EU's regulatory system worldwide and with it a devaluation of the CE-mark.
- Increased requirements for EU made products in view of registration and licensing in non-EU countries.
- Additional audits by or by order of national competent authorities from non-EU countries.
- Exclusion of EU medical device manufacturers from mutual acceptance of audit results/reports between the members states of the Global Harmonization Task Force, leaving them outside of meanwhile recognizable advances towards the global harmonization of regulatory requirements.
- Creating an additional administrative level in the process for assessing, notification and monitoring of conformity assessment bodies which will most likely result in cost increases.

EMIG is fundamentally open for any deregulation and an absolute proponent of the establishment of harmonized processes and requirements throughout the EU if such activities result in perceptible advantages for all parties involved in health care. EMIG is convinced that the draft provisions as specified in Article 19, §3, in particular the possibility to delegate the notification and monitoring, will lead to the opposite. EMIG is willing and available to propose and discuss solutions to the matter.