

“Vienna – Resolution”

Competent Authorities (CA's) on Medical Devices together in Vienna on the 3rd and the 4th of April 2006 express their concern at the proposals of the New Approach (SOGS N529 EN version 0.2). In particular the current discussion on the designation process, the role of accreditation bodies, the Essential Requirements for Notified Bodies and the concept of presumption of conformity of the EN 45000/ISO/IEC 17000 series of standards raised serious concerns.

The meeting of the Medical Devices Competent Authorities affirmed the essential role played by Notified Bodies in the operation of the medical devices regulatory system. To overcome various problems of some inconsistent performances by NB's, identified by the Commission in its Review into the Functioning of the Medical Devices Directive, a guidance document (MEDDEV 2.10/2) and the Notified Body Operations Group (NBOG) was set up several years ago with the task of improving the performance of Notified Bodies and those organizations responsible for their designation and control. So far NBOG has produced a set of documents, notably the Designating Authorities Handbook, arranged and provided training for DA assessors and is currently establishing a system of peer review of DA activities.

The meeting agreed that the above activities of NBOG have anticipated many of the concerns emerging in the current Review of the New Approach. Accordingly the Commission was asked

- that the unit of the Commission responsible for the review of the new approach takes note of the meetings concerns that imposition of certain recommendations emerging from that review could undo much of the excellent work already achieved within the medical devices sector,
- to take note that current activities in the medical devices sector to improve the Notified bodies performance is already contributing to the avoidance of possible adverse effects of low sector specific expertise and low compliance directly impacting patients health,
- to take note that the Medical Devices sector has already taken steps to improve the designation and surveillance of Notified Bodies and will continue to build on the progress made,
- to take particularly note that it would be an error to believe that designation of NB solely on the basis of conformity to the EN 45000/ISO/IEC 17000 series of standards is adequate, as these standards are not sufficient to demonstrate conformity with the Essential Requirements set out in the Medical Devices Directives.