



## Brdo Resolution

26 February 2008

The Competent Authorities for Medical Devices convening in Brdo, Slovenia, for their 21<sup>st</sup> Meeting on the 25<sup>th</sup> and the 26<sup>th</sup> of February 2008 discussed the current situation regarding the designation and monitoring of Notified Bodies in the medical devices sector as well as the upcoming challenges resulting from the revision of the New Approach.

The Competent Authorities for Medical Devices affirm the essential role of Notified Bodies in the operation of the medical devices regulatory system.

The required high level of protection for patients and users can only be ensured by a consistent application of common principles by Member States when designating and monitoring Notified Bodies.

The outcome of the last year's survey performed by the Notified Body Operations Group (NBOG) clearly revealed that despite enormous improvements in the past few years, the current practice of Designating Authorities in the medical devices area is still subject to variation. The Competent Authorities agreed, that

- all Notified Bodies have to work to a consistently high level of competence as a prerequisite to protecting public health and to ensure a high level of patient safety;
- the designation and monitoring of Notified Bodies should be in line with the NBOG Designating Authorities Handbook, which was approved by the Member States as recommended guidance;
- assessment based on general conformity assessment standards such as EN 45000/ EN ISO/IEC 17000 is not sufficient to demonstrate a full compliance with the requirements set out in the medical devices directives;
- surveillance activities (on-site visits, observed audits) by Member States of their Notified Bodies and subsequent measures should be intensified to further increase the confidence in the system;
- all Member States should actively participate in the NBOG peer review program to ensure consistent and equal diligence in the designation and monitoring system.

Based on the outcome of the survey and in line with the Bonn Resolution **the Competent Authorities therefore encourage the European Commission:**

1. to consider and produce clear legal interpretation on how the new regulation on the New Approach affects the designation and monitoring of Notified Bodies in the medical devices sector; and
2. to consider what further steps, including if appropriate legislative ones under Article 16 of 93/42/EC<sup>1</sup>, should be taken to achieve the highest level of care and scrutiny be taken by Member States in the designation and monitoring of Notified Bodies in the medical devices sector in line with the principles set out in the NBOG Designating Authorities Handbook.

<sup>1</sup> See 2007/47/EC, Art. 2, 17. a) ... "When appropriate in the light of technical progress, the detailed measures necessary to ensure a consistent application of the criteria set out in Annex XI for the designation of bodies by the Member States shall be adopted in accordance with the regulatory procedure referred to in Article 7(2)".