To: European Coordination Notified Bodies (NB-MED)
The European Association for Medical devices of Notified Bodies (Team-NB)

Brussels, 29 June 2012

Re: Central Management Committee (CMC) Decision No 3

Dear Mr. Jepson, Dear Ms. Schlemmer,

Our industry believes that it has and does meet the Essential Requirements related to information supplied by the manufacturer and, in particular, the address requirements as laid out in Directives 90/385/EEC, 93/42/EEC, and 98/79/EC. To date our members have not experienced any problems in being contacted by either Notified Bodies or Authorities on any regulatory matter.

Some of our member companies have alerted us to the fact that they are being challenged by Notified Bodies as to their implementation plans in order to comply with 'CMC decision No 3' by 1st September 2012.

We would like to reiterate that Eucomed, the European Medical Technology Industry Association, and EDMA, the European Diagnostics Manufacturers' Association, have serious concerns with regards to 'CMC decision No 3', in particular with respect to aspects of legal basis and certainty, proportionality and unnecessary administrative burden and costs. The decision as such interferes with the existing legal procedures concerning harmonised standards, thereby jeopardising legal certainty, devaluing the European regulatory framework and increasing the risk of national variances, as we have already observed in some Member States.

We understand that this matter is also being looked into by the European Commission. Therefore, and until the legal nature and status of the CMC's decision No 3 is clarified by the European Commission, we would like to respectfully request that Notified Bodies defer from acting upon this decision.

We look forward to a continued good collaboration,

Yours sincerely,

John Brennan

Director Technical & Regulatory Affairs, Eucomed

Jesús Rueda Rodríguez

Regulatory Affairs Director, EDMA