The British Standards Institute (BSI) has expressed concerns about the operation of the European CE system for assessing the safety of medical devices.

Called to give evidence at a Parliamentary inquiry, John Howlett of the BSI set out his fear that currently, if a medical device product is fails an assessment by one notified body in the EU it is possible for the manufacturer to simply seek approval from a notified body in another country until a CE certification is attained.

The inquiry also heard the need for greater consistency in the way in which European authorities assess medical devices and greater scrutiny of their respective performance, particularly in relation to their expertise in making relevant decisions about safe use.

The inquiry is looking into the regulation of medical implants in the light of the PIP breast implant and metal-on-metal hip replacement scandals.
European Commissioner for Health John Dalli recently confirmed that his Directorate General will be proposing reforms to the regulation of medical devices later in 2012.

More information **here** [1]

And **here** [2]
15 June 2012

Links
[1] http://www.google.com/hostednews/ukpress/article/ALeqM5hwF5SFHgTwhBij5nG6hdNDsVfMQQ?docId=N0260441
[2] http://www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/news/120613-implant-ev-session/