Dear Sir/Madam,

Xiros plc is a small/medium sized company based in Leeds, UK, and was one of the earliest UK companies to CE mark its products (January 1995). It continues to design and manufacture innovative textile based implants.

This company has always strongly supported the Medical Devices Directive with its New Approach base. We believe it is very effective in regulating products so as to ensure the maximum level of patient safety and well being. It is a model that other regulatory regions have tended to support, as opposed to (for example) the US FDA model. In fact, it has the potential to become almost a global model. We do not believe that a radical recast is at all necessary (as opposed to periodic reviews as took place in 2007). We believe such changes would be:

- Expensive for the Commission to develop and establish
- Burdensome, particularly for small and medium sized enterprises
- Have no greater effect on public safety that that possible through the periodic revision (as necessary to keep pace with technology and compliance issues)
- A step backwards towards a more centralized system.

Xiros plc strongly supports the position adopted by EUCOMED in their response to the public consultation.

Yours faithfully,

**Jim Rowland**
REGULATORY AFFAIRS AND QUALITY DIRECTOR

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