

**Joint plan for immediate actions**

<b>Issues identified</b>	<b>Envisaged actions</b>	<b>Timing</b>
<p><b>Functioning of Notified Bodies</b></p>	<ul style="list-style-type: none"> <li>• Commission to propose an <b>implementing measure, based on Article 16(2) of Directive 93/42/EEC</b>, to ensure a consistent application of the criteria to be met for the designation of Notified Bodies by the Member States</li> </ul>	<p>October 2012</p>
	<ul style="list-style-type: none"> <li>• <b>Check list detailing the items to be verified by the Notified Bodies during an audit</b> to be developed and adopted as a part of a <b>Commission Recommendation</b></li> </ul>	<p>September 2012</p>
	<ul style="list-style-type: none"> <li>• Member States to <b>revisit their list of designated Notified Bodies</b> and to provide the Commission with an <b>updated list of the Notified Bodies designated for Class III medical devices</b></li> </ul>	<p>September 2012</p>
	<ul style="list-style-type: none"> <li>• <b>Notified Bodies responsible for Class III medical devices to be audited</b> by a team involving national and Commission staff</li> </ul>	<p>As from 2013</p>
	<ul style="list-style-type: none"> <li>• Member States to require their designated <b>Notified Bodies to perform unannounced audits</b> of the manufacturers to which they have</li> </ul>	<p>September 2012</p>

	<p>delivered certificates. The frequency of these unannounced audits should be defined by the Commission in a <b>Commission Recommendation</b>, based on the risk of the devices, after consultation with the Member States</p> <ul style="list-style-type: none"> <li>• Member States to ask their <b>designated Notified Bodies to report back to their authority on the frequency and results</b> of these unannounced audits</li> <li>• Member States to ensure that the communication of <b>vigilance reports to the Notified Bodies</b> is part of the contractual arrangement between the manufacturers and their Notified Bodies</li> <li>• Possibility for <b>Notified Bodies</b> to be granted <b>access to vigilance reports contained in Eudamed</b>, subject to confidentiality principles</li> </ul>	<p>April 2012</p> <p>Discussion starting in March 2012</p>
<p><b>Market surveillance</b></p>	<p>Member States to <b>reinforce their market surveillance</b> in accordance with Directive 93/42/EEC and Regulation (EC) No 765/2008</p> <p>In particular</p> <ul style="list-style-type: none"> <li>• Member States to <b>perform appropriate checks</b> on the characteristics of products on an adequate scale, by means of</li> </ul>	

	<p>documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples.</p> <ul style="list-style-type: none"> <li>• Where necessary and justified, market surveillance authorities to <b>enter the premises of economic operators</b> and take the necessary samples of products</li> <li>• Member States to <b>report back to the Commission</b> on how they fulfil their information and organisation obligations laid down in Articles 17 and 18 of Regulation (EC) No 765/2008</li> <li>• Member States to <b>provide information on the powers, resources and knowledge</b> they make available for the proper performance of their market surveillance activities</li> </ul>	<p>July 2012</p> <p>July 2012</p>
<p><b>Coordination</b></p>	<ul style="list-style-type: none"> <li>• <b>Coordinated analysis</b> to take place when an increased frequency of vigilance reports is identified by a Competent Authority and/or by the Commission for a certain device or a certain type of device</li> <li>• <b>Coordinated inspection</b> on the market and in the premises of manufacturers / importers of such</li> </ul>	<p>As from July 2012</p>

	<p>devices established on the European territory by the concerned Competent Authorities to be organized, when appropriate, followed by the adoption of the <b>necessary corrective actions</b></p> <ul style="list-style-type: none"> <li>• <b>Increased coordination</b>, in particular in the field of audits and market surveillance, to be established in the framework of the confidentiality arrangements signed with <b>international partners</b></li> </ul>	<p>As from February 2012</p>
<p><b>Communication and transparency</b></p>	<ul style="list-style-type: none"> <li>• Commission to adopt a <b>Recommendation</b> providing general guidance to Member States regarding the establishment of a <b>unique device identification system</b></li> <li>• Commission to <b>engage a dialogue</b> with healthcare professionals and Member States about <b>implantation registers</b></li> <li>• Member States to <b>request healthcare professionals and encourage patients to report adverse incidents</b> involving medical devices to their Competent Authority</li> </ul>	<p>December 2012</p> <p>May 2012</p> <p>July 2012</p>