Joint plan for immediate actions

Issues identified	Envisaged actions	Timing
Functioning of Notified Bodies	• Commission to propose an **implementing measure, based on Article 16(2) of Directive 93/42/EEC**, to ensure a consistent application of the criteria to be met for the designation of Notified Bodies by the Member States	October 2012
	• **Check list detailing the items to be verified by the Notified Bodies during an audit** to be developed and adopted as a part of a **Commission Recommendation**	September 2012
	• Member States to **revisit** their **list of designated Notified Bodies** and to provide the Commission with an **updated list** of the Notified Bodies **designated for Class III medical devices**	September 2012
	• **Notified Bodies responsible for Class III medical devices to be audited** by a team involving national and Commission staff	As from 2013
	• Member States to require their designated **Notified Bodies to perform unannounced audits** of the manufacturers to which they have	September 2012

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	delivered certificates. The frequency of these unannounced audits should be defined by the Commission in a **Commission Recommendation**, based on the risk of the devices, after consultation with the Member States • Member States to ask their **designated Notified Bodies to report back to their authority on the frequency and results** of these unannounced audits	
	• Member States to ensure that the communication of **vigilance reports to the Notified Bodies** is part of the contractual arrangement between the manufacturers and their Notified Bodies	April 2012
	• Possibility for **Notified Bodies** to be granted **access to vigilance reports contained in Eudamed**, subject to confidentiality principles	Discussion starting in March 2012
Market surveillance	Member States to **reinforce** their **market surveillance** in accordance with Directive 93/42/EEC and Regulation (EC) No 765/2008 In particular • Member States to **perform appropriate checks** on the characteristics of products on an adequate scale, by means of	

	documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples. • Where necessary and justified, market surveillance authorities to **enter the premises of economic operators** and take the necessary samples of products • Member States to **report back to the Commission** on how they fulfil their information and organisation obligations laid down in Articles 17 and 18 of Regulation (EC) No 765/2008 • Member States **to provide information on the powers, resources and knowledge** they make available for the proper performance of their market surveillance activities	July 2012 July 2012
Coordination	• **Coordinated analysis** 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 • **Coordinated inspection** on the market and in the premises of manufacturers / importers of such	As from July 2012

	devices established on the European territory by the concerned Competent Authorities to be organized, when appropriate, followed by the adoption of the **necessary corrective actions**	
	• **Increased coordination**, in particular in the field of audits and market surveillance, to be established in the framework of the confidentiality arrangements signed with **international partners**	As from February 2012
Communication and transparency	• Commission to adopt a **Recommendation** providing general guidance to Member States regarding the establishment of a **unique device identification system**	December 2012
	• Commission to **engage a dialogue** with healthcare professionals and Member States about **implantation registers**	May 2012
	• Member States to **request healthcare professionals** and **encourage patients to report adverse incidents** involving medical devices to their Competent Authority	July 2012