SECTORIAL MARKET SURVEIILANCE PROGRAMME FOR MEDICAL DEVICES

2014

Country: Romania
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No.	No of EU legislation applicable	No of national legislation applicable	Sector	Description of the product or category	Monitorting motivation	Monitoring activity	Starting period of date	Development	Outcomes of further initives
1	Directive 93/42/EEC, 98/79/EC	GD no 54/2009; GD no 798/2003	medical devices	medical devices registered at competent authority	proactive	Manufacturers and authorised reprezentatives	all year	National initiative	Checks if products are in compliance with the Directive Reinspection Improvement of surveiillance activities
2	Directive 93/42/EEC	GD no 54/2009	medical devices	medical devices class III manufactured in Romania	proactive	Documents inspection/ /inspection on sight	all year	National initiative	
3	Directive 93/42/EEC, 98/79/EC 90/385/EEC	GD no 54/2009; GD no 55/2009; GD no 798/2003	medical devices	medical devices	reactive	Incidents/complaints	all year	National initiative, cooperation with CA, manufacturers	
4	Directive 93/42/EEC, 98/79/EC 90/385/EEC	GD no 54/2009; GD no 55/2009; GD no 798/2003	medical devices	medical devices notified at Competent Authority by distributors/importers	reactive	Documents inspection/ /inspection on sight	all year	National initiative	
5	Directive 93/42/EEC, 98/79/EC 90/385/EEC	GD no 54/2009; GD no 55/2009; GD no 798/2003	medical devices	medical devices	proactive	Visits to distributors/importers	all year	National initiative	

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6	Directive 93/42/EEC, 98/79/EC 90/385/EEC	GD no 54/2009; GD no 55/2009; GD no 798/2003	medical devices	medical devices	proactive	Medical device exhibitions	all year	National initiative	Checks if products are in compliance with the Directive
7	Directive 93/42/EEC, 98/79/EC 90/385/EEC	GD no 54/2009; GD no 55/2009; GD no 798/2003	medical devices	medical devices	proactive	internet distributors	all year	National initiative	Reinspection Improvement of surveiillance activities