

SECTORIAL MARKET SURVEILLANCE PROGRAMME FOR MEDICAL DEVICES

2014

Country: Romania

Authority for market surveillance: **Ministry of Health - Medical Device Department**

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No.	No of EU legislation applicable	No of national legislation applicable	Sector	Description of the product or category	Monitoring motivation	Monitoring activity	Starting period of date	Development	Outcomes of further initiatives
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 representatives	all year	National initiative	Checks if products are in compliance with the Directive
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	Reinspection Improvement of surveillance activities
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
									Reinspection
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	Improvement of surveillanc activities