

SECTORAL NATIONAL MARKET SURVEILLANCE PROGRAMME (Sectoral NMSP)

State: **Norway**

Surveillance Authority: **Norwegian Directorate of Health**

Planning for: **2014**

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No of EU legislation applicable	Sector	Description	Type of monitoring	Monitoring motivation	Monitoring activity	Priority	Time period	Outcomes or further initiatives	Contact
93/42/EEC	Medical devices	Teeth whitening products	Proactive	Lay and professional users	Inspection and cooperation with Customs Authority	High	Q1+Q2	National initiatives/cooperation with other EU-member state	Medisinsk.utstyr@helsedir.no
93/42/EEC	Medical devices	Dental fillers	Proactive	Risk assessments and compliance	Follow up after sample testing in 2013	High	Q1+Q2	National initiatives/cooperation with other EU-member state	Medisinsk.utstyr@helsedir.no
98/79/EEC	Medical devices	IVD In house production	Proactive	Risk assessments and compliance	Site inspection	High	Q3+Q4	National initiatives	Medisinsk.utstyr@helsedir.no
98/79/EEC	Medical devices	IVD	Proactive	Risk assessments and compliance	Desk review	Medium	Q1+Q2	National initiatives/cooperation with other EU-member state	Medisinsk.utstyr@helsedir.no
93/42/EEC 98/79/EEC	Medical devices	Medical device	Reactive	Vigilance incidents and complaints	Document inspection/Desk review/Site inspection	High	On going	National initiatives/cooperation with other EU-member state	Medisinsk.utstyr@helsedir.no