

Fédération Européenne
de l'Industrie
de l'Optique
et de la Mécanique
de Précision

European
Federation of
Precision
Mechanical and
Optical Industries

Europäische
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Feinmechanik
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e u r o m



EUROM VI "Medical Technology"

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Enhancing the health of the public European wide and world wide and
Facilitating innovation by harmonising the European and global regulatory environment

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Revision of the regulatory framework for medical devices – Classification Rule 19 (Nanomaterial)

EUROM VI supports the attached statement of the Federation of the European Dental Industry (FIDE) on the Commission's draft MDEG 06-02-2012, especially regarding the proposed change in the wording of the planned new Classification Rule 19.

A survey within our members has confirmed that nanoparticles are often contained as fillers in elastomers used in many medical devices, e.g. carbon black in O-ring seals, Aerosils in silicone hoses etc.

EUROM VI therefore recommends adopting the text proposed by FIDE to change the wording of the new Classification Rule 19. This will avoid the need for many medical devices being given Class III classification owing to the presence of nanoparticles. Unintended leaching of nanoparticles from medical devices is covered by Essential Requirement 7.6 of the proposed draft Regulation, and evaluation of the risks associated with these particles should be part of the manufacturer's risk management process.

EUROM VI is the committee for Medical Technology within the European Federation of Precision Mechanical and Optical Industries and represents mainly European small and medium-sized enterprises.

The objectives of EUROM VI are:

- to represent European Medical Technology Industry;
- to promote cooperation between members but also with other European organisations;
- to encourage worldwide trade by being involved in harmonisation of legislation, standardisation, mutual recognition and certification procedures;
- to be a partner on works with the European Commission and Standardisation Bodies;
- to defend European Industry views on international activities.