Nanomaterials

AmCham EU Healthcare Breakfast Meeting

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- Nanomaterials containing devices are subject of specific points of the Annex 1 (specific risk assessment and labels).
- This is aligned with Food, cosmetic and medicinal drug regulations.
- Up-classification in class III specifically for devices which have an intended release of nanomaterials in the human body.

2012 EU Commission Rule 19 Definition proposes to up-classify all nanomaterials containing devices unless these nanomaterials “cannot be released”.

From a scientific point of view, proving zero-release is impossible.

The current proposal will lead to the up-classification of almost 75% of the dental medical devices (tooth filling material, crowns,..).