EU's new medical device regulations: 5 questions with Eucomed's Serge Bernasconi

Mass Device

MassDevice.com looks at key issues in the European Commission's newly released medical device regulatory guidelines with Eucomed's Serge Bernasconi.

As medical device companies digest the European Commission's newly released medical device regulatory recommendations, **MassDevice.com** caught up with Serge Bernasconi, CEO of Eucomed and the European Diagnostic Manufacturers Assn. (EDMA), to discuss how the creation of a central FDA-like body to oversee pre-market medtech review for the European Union might impact the broader device industry.

On Wednesday, medical device groups were quick to criticize [1] aspects of the new regulatory guidelines, which still need to clear hurdles before final implementation, saying certain updates stall innovation rather than bolster safety.

European authorities have been assessing medtech review standards, which haven't changed much in 2 decades, since the European Commission in 2008 identified several vulnerabilities. Regulators came under intense pressure to revise security standards for medical devices after a wide-scale breast implant recall dramatically exposed weaknesses in the system.

We caught up Bernasconi, the former president and international regional VP of Medtronic [2] (NYSE:MDT [3]) France who turned industry advocate, for his take on the issue.

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