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Industrialization

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Placing on the market a Medical Device is subject to regulation in most of jurisdictions to ensure safety for patients and health care personnel. A new medical device needs to undergo a conformity assessment before being placed on the market and is subject to surveillance during its lifetime to ensure its safety and correct performance. According to the potential risks posed by the medical device, the conformity assessment follows different routes and can involve or not external accredited organisms. Additionally, the manufacturer is responsible to maintain the safety and performance of the medical device for its whole lifetime once it is placed on the market. This talk focus on the medical device regulations of the United Stated and Europe by going through the steps for placing and maintaining a medical device on the market and clarifying the role and responsibilities of the different stakeholders.

Primary author: BRUSASCO, Caterina

Presenter: BRUSASCO, Caterina