Exploring the Intersection of REACH, CLP and EU MDR

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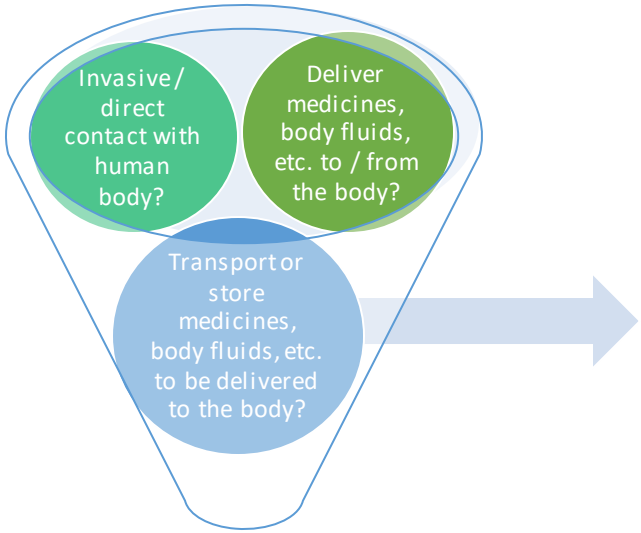
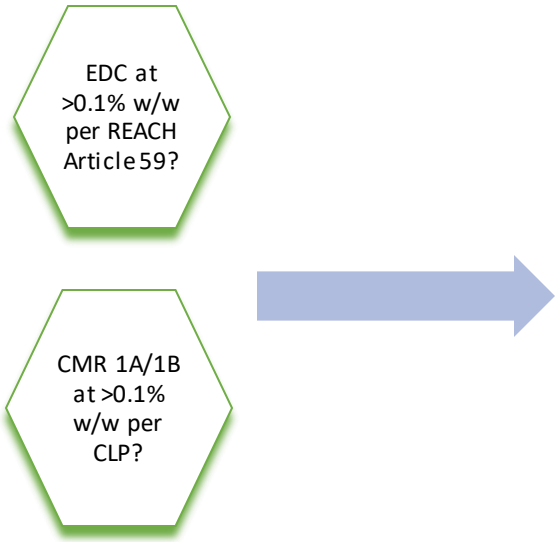
Abstract

Since the promulgation of the new EU Medical Device Regulation (MDR) in May 2017, medical device manufacturers have been preparing for the upcoming mandatory compliance date of May 2020, after which significant new labeling for devices containing carcinogens, mutagens, reproductive toxicants (CMR) and/or endocrine disrupting chemicals (EDC) will be required. This poster examines the specific criteria from EC 1272/2008 (CLP) and EC 1907/2006 (REACH) that will trigger label declaration and justification under EU MDR. Specific considerations depending on use and composition are also addressed.

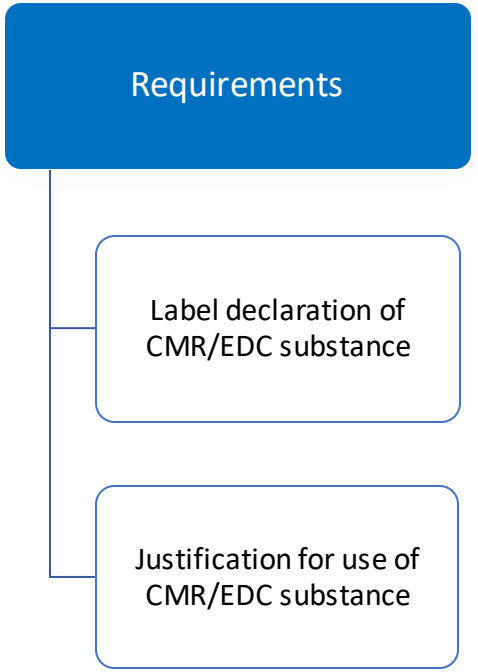
1. Evaluate the use of the device



2. Evaluate the device's composition



3. Determine the implications



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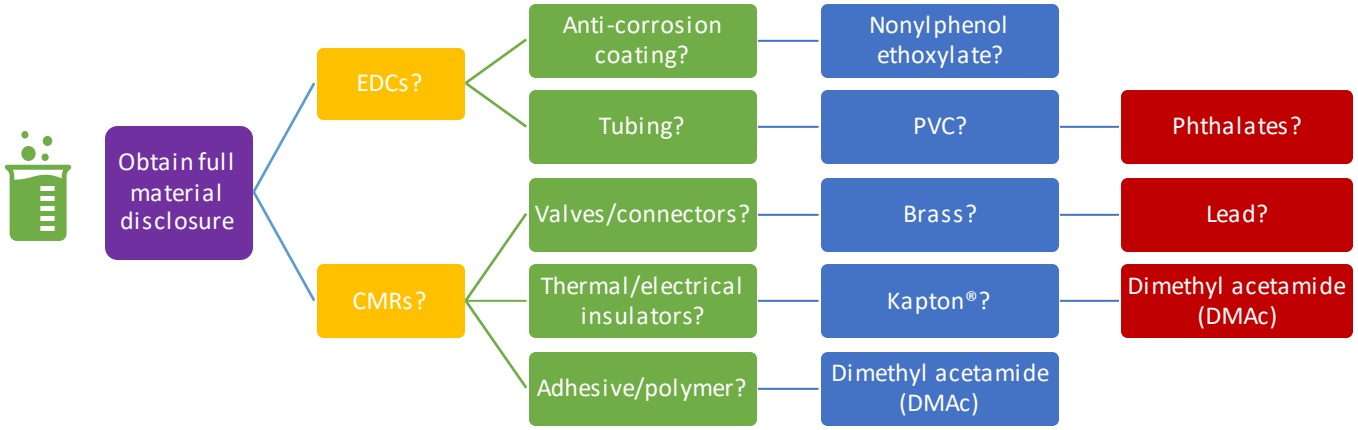
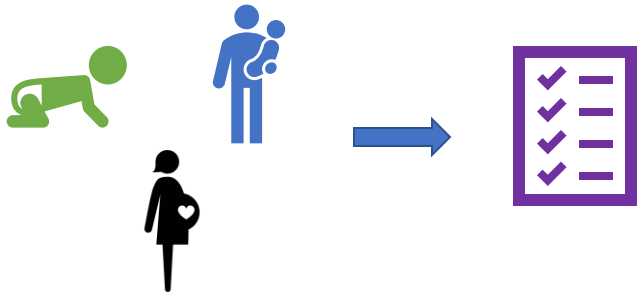
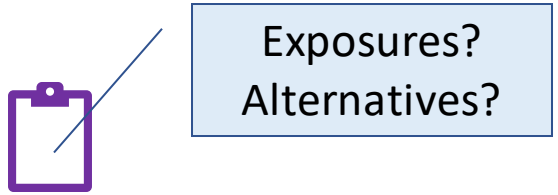
Specific Considerations



Material composition information from first tier suppliers may not be sufficient; disclosures from multiple tiers of suppliers may be needed to drill down



If device is for children, pregnant or nursing mothers, special precautions required in Instructions For Use



Justification for use of CMR/EDC must include possible exposures and analysis of alternatives