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Over The Counter 7 Aug 2023: What Happens To Software As A Medical Device Under The EU AI Act? With Bristows' Jamie Hatzel

by [David Ridley](#)

In the second part of HBW Insight's interview with Bristows' digital health regulatory expert Jamie Hatzel, we talk about artificial intelligence. Hatzel discusses what happens to Software as a Medical Device within the incoming EU artificial intelligence legislation, which has now entered trilogue negotiations. Issues such as the meaning of "high risk" within the proposed AI Act, in contrast to its meaning in the existing Medical Device Regulations, highlight the importance for manufacturers in this space, or thinking about entering it, of getting good advice, Hatzel points out.

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