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Over The Counter 24 July 2023: What Is 'Software As A Medical Device' And How Is It Regulated In Europe? With Bristows' Jamie Hatzel

by [David Ridley](#)

Digitalization is a hot topic in consumer health, and “digital health” covers a broad spectrum of applications, from wellness apps to virtual reality therapeutics. In this episode of Over The Counter, HBW Insight speaks to Jamie Hatzel, regulatory associate at law firm Bristows, to get some clarity on “software as a medical device” – a subset of medical device regulatory frameworks within which many digital health applications are classified. In the first part of a two-part podcast, Hatzel outlines the UK and EU regulatory approaches to SaMDs, before we discuss specific examples such as symptom trackers, wellness apps and digital therapeutics.

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