



Biotextiles as medical implants: 7. Regulation of biotextiles for medical use (Woodhead Publishing Series in Textiles)

E. Duncan

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The chapter describes the regulatory framework applicable to medical devices, and specifically to biotextiles, principally in the United States, but also in the European Union. With the emergence of new technologies and materials, new forms of regulation have become necessary, and some of the traditional classifications no longer match present-day applications. Problems encountered by manufacturers with regard to premarket approval clearance and material supply quality standards assurance are discussed, as well as issues increasingly arising when one biotextile-based medical device is evolved into another for a different use.

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