"Make in India" initiative extends to medical devices - India's new medical device rules are now in effect

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Medical Device Alert

In January 2017, India's Ministry of Health and Family Welfare released the long-awaited Medical Device Rules of 2017 (MDR 2017 or the Act), which took effect on January 1, 2018. Upon implementation, this regulation replaced the existing Drugs and Cosmetics Act (DCA) as it pertained to medical devices.

Prior to implementation of the Act, the medical device industry in India was largely unregulated, except for a few devices covered specifically by the DCA. The list of covered devices was limited (only 15 medical devices were included), and the DCA treated these devices as drugs rather than establishing regulations tailored to the medical device industry. The implementation of MDR 2017 attempts to establish a uniform regime for Indian medical device manufacturing and marketing.The structure of this regulatory paradigm appears to be on par with global norms, including the European Union's Medical Device Regulation, although the extent of these similarities will depend upon India's implementation of the Act.

Read More: "Make in India" Initiative Extends to Medical Devices - India's New Medical Device Rules Are Now in Effect

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