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This did not create a significant problem for medical device manufacturers but, for component manufacturers, logistics companies and the like, working to ISO 13485:2016 for medical device sector customers and to ISO 9001:2015, with its HLS – High Level Structure – for their other customers created needless additional administrative burden and, frankly, was a waste of time.

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INTERNATIONAL ISO STANDARD 13485

ISO 13485:2016 can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations. Requirements of ISO 13485:2016 are applicable to organizations regardless of their size and regardless of their type except where explicitly stated.

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Manufacturers holding only ISO 13485 certification with BSI are required to transition to ISO 13485:2016/EN ISO 13485:2016 by 28th February, 2019. The harmonization of EN ISO 13485:2016 is another step towards compliance to the recently published Medical Devices and IVD Regulations, which will supersede the current Directives in three and five years, respectively.

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