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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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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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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.

Another Revision of ISO 13485 starts in 2019

For more information about the changes, see our ISO 13485:2016 factsheet, which is available for download here. The necessary transition of your certificate is as follows: Since the official publication of ISO 13485:2016 on March 1, 2016, the transition of

accredited certifications to the new ISO 13485:2016 can now be effected within the scope of a regular surveillance or recertification audit.