IEC 62304 Ed. 1.0 b:2006, Medical device software - Software life cycle processes

By IEC TC/SC 62A

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Defines the life cycle requirements for medical device software. The set of processes, activities, and tasks described in this standard establishes a common framework for medical device software life cycle processes. Applies to the development and maintenance of medical device software when software is itself a medical device or when software is an embedded or integral part of the final medical device. This standard does not cover validation and final release of the medical device, even when the medical device consists entirely of software.

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