



ARAZY GROUP
Medical Device Consultants
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**IEC 62304:2006 – MEDICAL DEVICE SOFTWARE – SOFTWARE LIFE
CYCLE PROCESSES.**

Principal Features

The standard for Medical Device Software IEC 62304:2006 defines the life cycle requirements for medical device software. The set of processes, activities, and tasks described in this standard establish a common framework for medical device software life cycle processes. It is applicable 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. On the other hand, it does not cover validation and final release of the medical device, even when the medical device consists entirely of software.

This standard is an evolution of current software risk management and of the development life cycle process requirements comparing with the rules established in IEC 60601-1-4 and FDA guidance documents, although does not introduce new concepts. The safety classification system is based on concept from FDA guidance documents, focusing the risk management on the severity that the risk that is being mitigated represents, for the patient as the operator.

In order to avoid the problematic determination of probabilistic figures, alternative standard approaches propose to scale safety demands according to worst-case scenarios. This standard requires the classification of software components according to the harm their failure could cause and then requires software processes to be chosen dependant on the classification.

Higher burden of development life cycle controls corresponds to the higher safety classification. This applies for example to the licensing of software for medical devices as shown in the following table:

Safety classification according to IEC 62304

Class A

No injury may occur to the patient or to the operator resulting from a hazard to which the software item may be a contributing factor

Class B

Non-serious injury may occur to the patient or to the operator resulting from a hazard to which the software item may be a contributing factor

Class C

Death or serious injury may occur to the patient or to the operator resulting from a hazard to which the software item may be a contributing factor

Annexes

At the end of this standard there are several helpful Annexes. Amongst others, it includes Annex C, which explains the relationship of IEC 62304 to other standards, like ISO 14971, ISO 13485, IEC 60601-1-4, IEC 61508-3, and ISO 90003.

For more information see the IEC website at: www.iec.ch