

# 1 Preface

Digitalization in all areas of health care is becoming ever more ubiquitous, and medical software is the epitome of this phenomenon. Within the last few years its importance in hospital and outpatient settings has undergone a dramatic rise. The term “medical software” generally means software used in a therapeutic or diagnostic context. The medical software market offers numerous complex types of products with a multitude of uses. When taking a basic simplified regulatory view, medical software falls into two categories: embedded software as an integral part of a medical device, and stand-alone software as a medical device in its own right.

As demonstrated impressively in this guideline, the different requirements must already be taken into account while the medical device is still under development. The requirements are detailed in standards. The development of a legally compliant, and thus marketable product vitally depends on strict adherence to these standards. Recognizing this, the authors of this guideline have provided a valuable service by cutting a path through the standards jungle. As if that were not enough, by incorporating the latest European legal framework into their work, they also provide a glimpse of the immediate future.

In short, this guideline is outstanding and deserves appreciative reception.

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