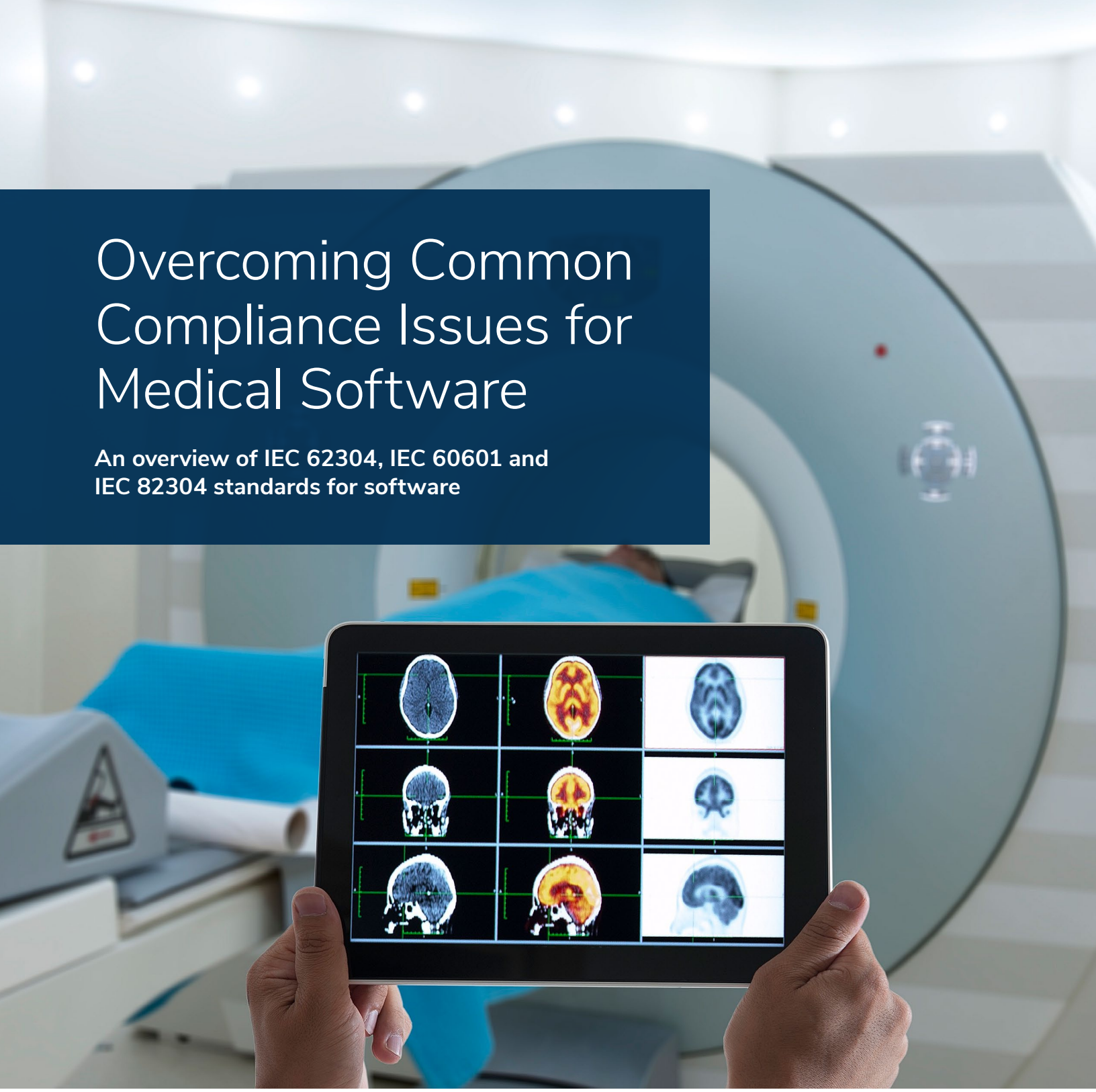


Overcoming Common Compliance Issues for Medical Software

An overview of IEC 62304, IEC 60601 and IEC 82304 standards for software

Sarah Mundim
Senior Consultant,
Quality and Regulatory Affairs
sarah.mundim@ul.com

EMERGO
by UL

May 2024

The rise of stand-alone medical software

The role of software is a significant area of growth in medical devices. Software can function as an integral component or an accessory of a medical device, or as an independent stand-alone device, which includes recent software applications on mobile devices.

In the past, low barriers to market entry have resulted in some software products being made available without due consideration of the potential risks to users and patients. Some of the reasons for this have been a lack of standards to guide developers, as well as a lack of regulatory clarity. (It was not always clear what regulations apply or if a software product itself qualified as a medical device.) In recent years, though, regulatory authorities have been working hard to provide better guidance.

Regulatory authorities across the globe are increasingly aware of the need to regulate software in medical devices and as stand-alone products. The European Union (EU) explicitly recognized some software-only products as medical devices when the Medical Devices Directive (MDD) 93/43/EEC was amended in 2007 and further expanded the definitions and requirements for medical device software in the Medical Devices Regulation (MDR) 2017/745 published in 2017, which replaced the MDD. Several regulatory authorities and associated groups, including the U.S. FDA and the EU Medical Device Coordination Group (MDCG), have issued various guidance documents related to software in or as medical devices.

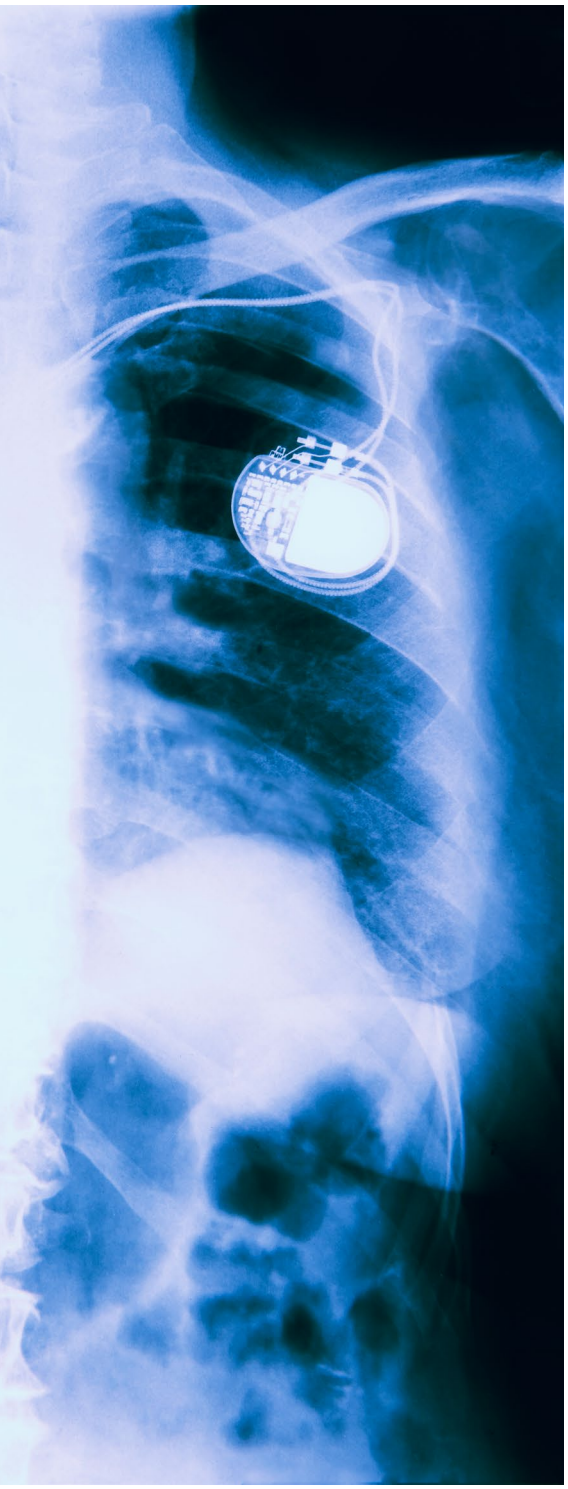
Software used for the design and manufacture of a device would not be considered a device itself, nor would software used to transmit administrative data (patient name and address).

When is software considered a medical device?

One key question medical software developers face related to compliance with regulations and international standards is whether or not their products qualify as medical devices. The prevalence and complexity of software in medical products have increased, which makes it difficult to determine whether some software products perform as actual medical devices — and must meet the same regulatory requirements as more established devices.

To start with, as simply put by the Medical Device Regulators Forum (IMDRF), it must be determined whether the software is “intended for one or more medical purposes.” The FDA and the EU specifically reference the definition of a medical device in their respective regulations: If the software’s intended use and indications for use fall into the definition of a medical device, then it will be regulated as a medical device.

Software that is driving or influencing the use of a medical device is generally covered by the medical device regulations either as a part/component of a device or as an accessory for a medical device. If the software stands alone from any hardware as it performs the functions that categorize it as a medical device, also called software as a medical device (SaMD), then it is regulated as a medical device in its own right.



Classification of medical device software

Thus, software may be viewed as a medical device, an accessory to a medical device, or a component and integral part of a medical device (automatically in the same class as the medical device and subject to the conformity assessment of the medical device).

The software's function dictates the classification. If the software is a medical device or a medical device accessory, it will be assigned a risk class corresponding to its medical purposes/indications. Under the EU MDR, for example, stand-alone medical device software is subject to Rule 11 and may be assigned a classification of Class I to Class III depending on overall risk. If the software medical device is an integral component of a device as indicated above, it assumes the classification of the device. For example, software that is part of a Class III medical device is assumed to be Class III as well.

Software as a medical device with a measuring function

Medical software may be considered to have a measuring function if it has specific characteristics: quantitatively measures a physiological function or anatomical parameter; displays measurements in legal units or other acceptable units; and its intended purpose implies accuracy and failure to comply with a measurement could adversely affect a patient's health and safety.

Determining routes to compliance

To determine the proper route to compliance for your software, consider the following questions:

- Is the software a component/integral part of a medical device?

  If yes, in most regions, it will be considered part of the medical device. The software will have the same class as the device and will be covered in the medical device technical file documentation.
- Is the software intended to serve as a medical device? That is, is it intended to diagnose, prevent, monitor, treat or alleviate disease, or to provide information related to one of these medical purposes?

  If yes, in most regions, the software is considered an SaMD.

Key standards for medical device software

The breadth and depth of standards and guidance documents addressing medical device software have expanded in recent years. Significant standards related to such software are summarized below. Guidance documents are specific to regions and should be considered for markets of interest.

IEC 62304: Medical device software

The standard IEC 62304, Medical device software - Software life cycle processes, covers both software as a component of a medical device (software in a medical device, or SiMD) and stand-alone software (SaMD in its own right). IEC 62304 has been recognized in many jurisdictions as a best practice for the design and development of medical device software.

IEC 62304 focuses on the idea that developing safe medical software requires both quality management and risk management, and introduces a risk-based software safety classification system based on three classes: A, B and C. It is important to note that this system of software safety classification is separate from various regional systems of medical device classification. IEC 62304 then provides recommendations and requirements for various activities and documentation to support the safety and reliability of the software.

When IEC 62304 was first published in 2006, many industry and conformity assessment bodies questioned its implementation. In 2015, the standard was amended to answer many questions, including clarifying what a risk-based approach was and how to deal with legacy software.

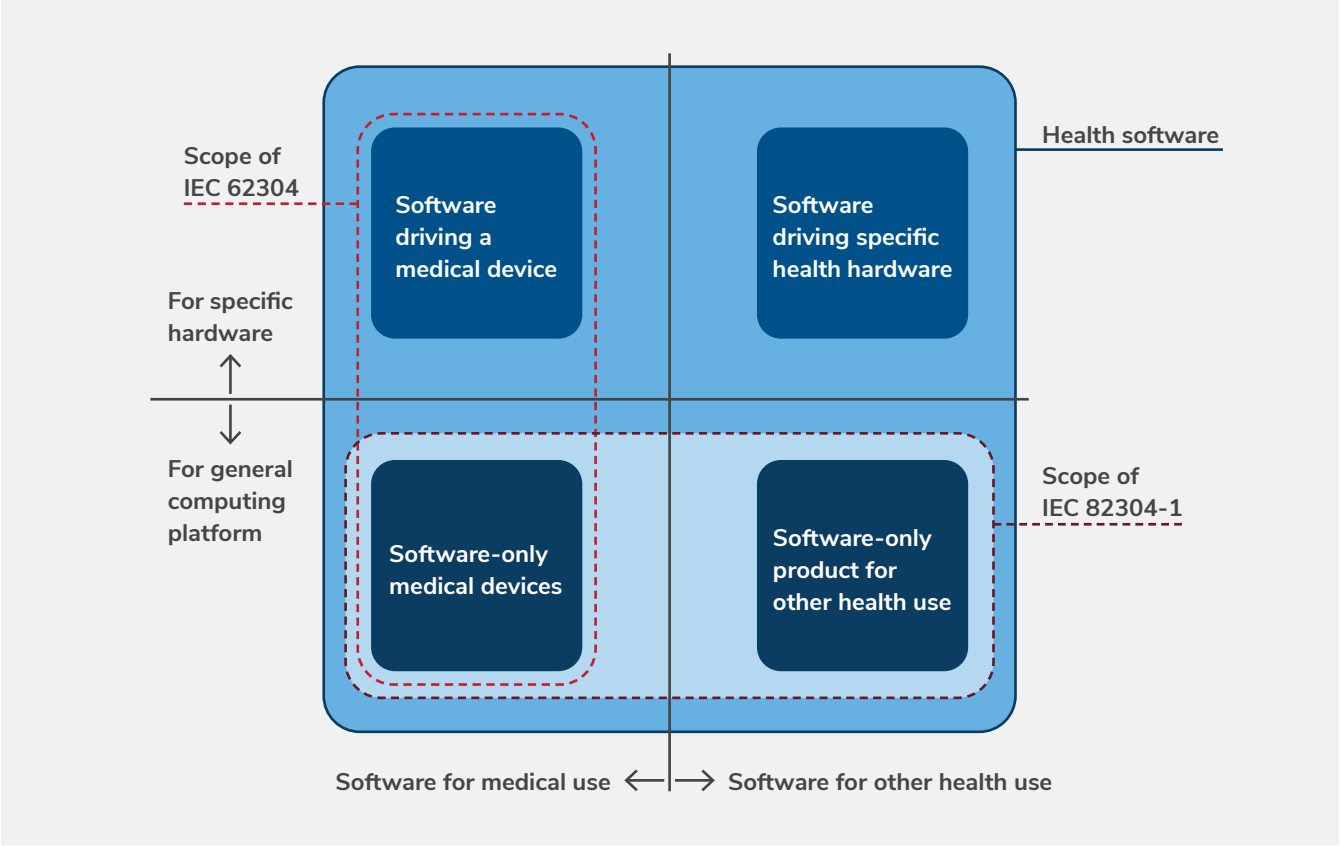
IEC 82304: Product safety for health software

The IEC 82304 Series of Standards was developed to address key concerns for stand-alone software devices more clearly, including those that are SaMD. In these standards, health software is defined as software intended to be used specifically for managing, maintaining or improving the health of individual persons or the delivery of care.

The standards recognize that the concept of risk in healthcare may need to be redefined. Previously, risk was associated with direct physical damage or indirect damage (such as misdiagnosis or delay in diagnosis), whereas data integrity, breach of security and privacy are more recent potential sources of harm.

IEC 82304-1, which focuses specifically on the safety of health software, pays particular attention to connected devices and cybersecurity risks. A joint effort by the electromedical and health informatics groups of the IEC, it also addresses health applications intended to be used in combination with general and mobile computing platforms. A key benefit of IEC 82304-1 is that it bridges the gap between software verification in IEC 62304 and the validation requirements mandated by medical device regulations in many jurisdictions. It also clearly defines and differentiates ”user” and “responsible organization,” which is important for product validation and commercialization. Indeed, it is intended to complement the use of IEC 62304 and is not for use alone.

The figure below depicts the scope of health software and the scope of the standard IEC 82304-1.



Adapted from IEC 82304-1, Annex A, Figure A.1, Health software application domains and scope of related standards.

The IEC 80001 Series and other approaches to risk management for connected software

IEC 62304 and IEC 82304-1 focus on software manufacturers but do not address accountability. Who takes responsibility for integrating multiple medical devices and software systems into an IT network?

To address this question, an international working group started developing the IEC 80001 Series of documents, with the first published in 2010. These are focused on risk management for IT networks incorporating medical devices.

Regarding cybersecurity, IEC 81001-5-1 lays out the activities manufacturers need to perform to provide protection against cyber threats. It follows the life-cycle stages laid out in IEC 62304, but with emphasis on cybersecurity as opposed to safety. IEC 81001-5-1 is an FDA-recognized consensus standard and is expected to be harmonized under EU MDR/IVDR soon. The UL 2900 Series has also been developed to help address cybersecurity threats for software in healthcare but is not limited only to SiMD and SaMD. Although, the UL 2900 Series is not currently mandatory, it is viewed as a gold standard for helping reduce security risks and should be considered for higher-risk software.

AAMI TIR57 provides additional information on how to evaluate risk for software and can help confirm that risks are adequately analyzed and documented, including those related to cybersecurity.

Toward a common framework for health software

The IEC 60601-1 standard and integrated medical device software

Another important standard for integrated medical device software is IEC 60601-1. While primarily about electrical safety and essential performance, the standard has significant information regarding software and is always useful for reference. Particularly worth noting is that for integrated medical device software, i.e., SiMD, Clause 14 of the standard contains the requirement for validation, thereby bridging the gap between verification and validation.

Conclusion

As software becomes more important in the overall healthcare ecosystem, both as SaMD and SiMD, developers and manufacturers must consider the potential risks to patients and users. However, now that standards and regulations have started addressing risks and regulatory issues concerning medical device software, companies have a clearer picture of what compliance means for their products and technologies. Companies are advised to comply with IEC 62304 and, where relevant, IEC 82304 and IEC 60601-1. Additionally, they should consider compliance with the IEC 80001 Series, ANSI/UL 2900 Series, IEC 81001-5-1 and AAMI TIR57, as applicable, depending on current best practices in the jurisdiction of interest.

Learn more

Need help with global regulatory consulting? Emergo by UL helps medical device companies with regulatory compliance and market access in markets worldwide. Here's how we help:

- ISO 14971 risk management consulting
- Device classification and assessment
- Clinical literature reviews and CER preparation

Learn more about global market access for medical devices at **EmergobyUL.com**.

About the author

Sarah Mundim is a senior consultant at Emergo by UL based in Brasília, Brazil. Mundim holds a bachelor's degree in biological sciences and has over 11 years of experience in regulatory affairs. Mundim's regulatory expertise includes Brazil registrations as well as U.S. FDA 510(k) submissions, MDR TDF and CER compilation, and review for a large variety of medical devices, including SaMD.

EMERGO

by UL

RLC24CS1577600