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## Med-Info

International expert information  
for the medical device industry

## 3<sup>rd</sup> edition of IEC 60601-1:2005+A1:2012

### This Med-Info is addressed to

- Manufacturers of medical electrical equipment and systems
- Manufacturers of components of medical electrical equipment

### Background

The IEC 60601-1:2005 (3<sup>rd</sup> edition) was published in December 2005. It is the 3<sup>rd</sup> edition of the basic standard, replacing the previous version IEC 60601-1:1988+A1:1991+A2:1995.

Amendment 1 (A1:2012) was published in July 2012. The current version of the standard is thus called IEC 60601-1:2005+A1:2012, also known as Edition 3.1.

As basic standard for medical electrical equipment, this standard deals with the general requirements concerning basic safety and the essential performance.

### What is the new standard called?

IEC 60601-1:2005+A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. The German version is published as DIN EN 60601-1:2013.

### Why did a new edition of the basic standard become necessary and which are the most important changes compared to the second edition?

- a) User protection was adjusted to the requirements of IEC 60950-1 for information technology. This has often led to alleviated requirements and thus allows, under certain conditions, the use of components already approved in IEC 60950-1.
- b) Introduction of risk management as an alternative for compliance of individual aspects of the standard and for covering risks not subject to a standard.
- c) More precise adjustment of the insulation coordination to environmental conditions (e.g. degree of pollution, overvoltage category, etc.).
- d) Integration of some collateral standards into the basic standard (e.g. IEC 60601-1-1 systems).
- e) Expansion of the scope of application of the standard beyond basic safety by integration of the essential performance (= functional safety).
- f) The most national deviations for America (previously in UL 60601-1) have been included in the 3<sup>rd</sup> edition.
- g) Introduction of the term "expected service life".
- h) Section 9, "Mechanical hazards", has been expanded significantly.
- i) Key changes in A1:2012:
  - correction of problems that emerged when the standard was applied
  - reduction of references to risk management
  - clarification of the term "Essential Performance"

# Iec 60603rd Edition Amendment 1

**Ying Liu**



## **Iec 60603rd Edition Amendment 1:**

## **Iec 60603rd Edition Amendment 1 Book Review: Unveiling the Magic of Language**

In an electronic era where connections and knowledge reign supreme, the enchanting power of language has been apparent than ever. Its capability to stir emotions, provoke thought, and instigate transformation is actually remarkable. This extraordinary book, aptly titled "**Iec 60603rd Edition Amendment 1**," compiled by a highly acclaimed author, immerses readers in a captivating exploration of the significance of language and its profound impact on our existence. Throughout this critique, we will delve to the book's central themes, evaluate its unique writing style, and assess its overall influence on its readership.

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### **Iec 60603rd Edition Amendment 1 Introduction**

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