

# UNE-EN IEC 81001-5-1:2022 Healthcare software and health IT systems safety



## What is the UNE-EN IEC 81001-5-1:2022 standard?

**Healthcare software** plays a vital role in the delivery of healthcare. But, like any system, they can also be vulnerable to cyber-attacks. The UNE-EN IEC 81001-5-1:2022 standard refers to the following:

- Software integrated into medical devices.
- Software included in hardware designed for healthcare purposes.
- Standalone software products intended for healthcare applications.

## The objectives of the UNE-EN IEC 81001-5-1:2022 standard

**IEC 81001-5-1:2022** establishes safety requirements for healthcare software and HITS. These requirements apply to all phases of the product life cycle, from planning and design to implementation, maintenance and retirement.

## Who is the UNE-EN IEC 81001-5-1:2022 standard aimed at?

UNE-EN IEC 81001-5-1:2022 is aimed at the following types of organisations:

- Providers of healthcare software and healthcare information systems
- Users of healthcare software and healthcare information systems

- Regulatory authorities

## The benefits of the implementation and certification of the UNE-EN IEC 81001-5-1:2022 standard

UNE-EN IEC 81001-5-1:2022 has the following benefits:

- Improved safety of healthcare software
- Increased customer satisfaction
- Regulatory compliance
- Improved quality of healthcare software
- Increased customer satisfaction
- Cost reduction
- Improved competitiveness

## Why certify the UNE-EN IEC 81001-5-1:2022 standard with Applus+ Certification?

[Applus+ Certification](#) is an independent entity of recognised prestige whose objective is to help organisations achieve their commitment to continuous improvement.

We analyse our clients' needs so that our auditors, specialists in each sector of activity, can provide a service that provides maximum value when assessing your organisation's compliance.

Our teams develop specific certification plans based on our clients' structure, processes and activities.

Our international presence, extensive product portfolio and accreditations enable us to provide a global, expert service tailored to your organisation's needs.