

## European standardization on healthcare

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The European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) are two officially recognised organisations (EU [Regulation 1025/2012](#)) responsible for developing standards at European level .

The members of CEN and CENELEC are the National Standards Bodies of 33 European countries including all of the EU member states plus Iceland, Norway, Switzerland, Former Yugoslav Republic of Macedonia and Turkey. CEN and CENELEC also work to promote the international harmonisation of standards in the framework of technical cooperation agreements with ISO (International Organization for Standardization) and IEC (International Electrotechnical Commission).

Standards are documents of a voluntary character that set out specifications and other technical information in relation to products, procedures, systems, test methods or services. They cover a wide variety of topics, including healthcare. One of the biggest benefits of European Standards is their identical implementation across Europe and the obligation of National Standards Bodies to withdraw any existing conflicting national standards. Although European Standards remain voluntary in application for manufacturers or service providers, this ensures that there is a common reference within the 33 countries.

Traditionally standardization in relation to the healthcare sector has focused on medical devices, medical equipment and e-health applications. European standards in these areas support the implementation of European legislation and contribute in a significant way to the safety and quality of medical devices on the European market and the interoperability and effectiveness of healthcare ICT applications and information.

In recent years, there has been an increasing level of demand from stakeholders in relation to the standardization of healthcare services. European standardization is seen as an important tool in order to increase the quality of the services offered, patient safety and efficiency of healthcare systems, which is important within the current context of increasing mobility of patients and health professionals, economic crisis and ageing population. Taking into account these developments, CEN and CENELEC are currently trying to define a strategy on how to approach standardization in the area of healthcare services.

Standardization is based on the principles of transparency, openness and consensus amongst the different interested parties in a specific area (patients, healthcare professionals, public authorities, nurses and other stakeholders committed to participate). Standards can be useful tools for professionals and it is important to get involved in their development. CEN and CENELEC cooperate with many European organisations in the development of standards. We are looking forward to having the opportunity to cooperate with EUNETIPS.