



ISO and health

Great things happen **when the world agrees.**

We are ISO,
the International Organization
for Standardization



We are an independent,
non-governmental organization.



We are a global network of
national standards bodies with
one member per country.



Our job is to make International
Standards.



We are coordinated by a Central
Secretariat in Geneva, Switzerland.



We are not for profit : selling our
standards allows us to finance
their development in a neutral
environment, to maintain them
and to make new ones.



ISO provides a platform for
developing practical tools through
common understanding and
cooperation with all stakeholders.

163* members

21350*
International Standards

100
new standards each month

238*
technical committees

ἴσος

Notice that our acronym
doesn't match our name ?

It's not meant to.

"ISO" is derived from
the Greek word *isos* (equal),
so that it's the same in
all languages.

* September 2016

In 2013, nearly **9%** of the gross domestic product (GDP) of most developed nations (OECD countries) was spent on healthcare*—an enormous part of a country's economy.

More than **1300*** ISO health standards help to ensure these aspirations are achieved.

Good health and well-being are one of the UN Sustainable Development Goals, the United Nations' new roadmap to improve people's lives **by 2030.**

* Source: www.oecd.org

Why do we need ISO standards for health?



Access to:

- health services
- quality care
- safe medical practices and equipment
- cost-effective solutions

has become the expected norm of today's society.



ISO works through its network of national members to bring together the foremost international expertise and disseminate it globally.



ISO standards for health help ensure that individuals and communities receive the quality of care they deserve.



By implementing ISO standards, organizations and companies make a proactive commitment to the principles of quality, transparency, accountability and safety.



ISO standards make it easier to compare health services, exchange information, aggregate data and safeguard the privacy of an individual's health.



Who benefits from ISO standards for health ?

□ Industry

ISO health standards ensure consistency. Healthcare providers, national governments and manufacturers benefit from not having to comply with multiple specifications and requirements for different markets.

ISO standards are strategic tools that help businesses gain a competitive advantage through products and services that are safe, reliable and trustworthy.

□ Regulators

Regulators can rely on trusted internationally harmonized solutions, which are continually reviewed and improved to provide the technical foundation for market-friendly regulations that meet citizens' expectations.

ISO standards provide tools to assess and evaluate conformity, affording a solid technical base for health legislation.

□ Consumers

ISO standards safeguard consumer interests by ensuring good-quality care and safe and reliable products and services.

ISO standards seek to harmonize the healthcare sector to reduce costs, thereby facilitating access to care and increasing efficiency.



What health sectors does ISO cover ?

Standardization in the field of health covers a variety of sectors, for instance:



Dentistry



Surgery



Optics



Assistive products for persons with disabilities



Equipment for transfusions



Sterilization of healthcare products



Infusions and injections



Health informatics



Medical devices



Traditional Chinese medicine

What standards does ISO have for health?

Below is a selection of ISO technical committees dedicated to improving the safety and quality of healthcare worldwide.

Quality management and risk management

ISO standards for health help to ensure the safety and effectiveness of health products through proficient quality and risk management.

- **ISO/TC 212**, *Clinical laboratory testing and in vitro diagnostic test systems*
- **ISO/TC 210**, *Quality management and corresponding general aspects for medical devices*

Occupational health and safety

- **ISO/PC 283**, *Occupational health and safety management systems*

This health committee is responsible for the development of ISO 45001, an upcoming ISO standard.

- **ISO/TC 94**, *Personal safety – Protective clothing and equipment*

This health committee is charged with standardizing the quality and performance of clothing and personal equipment designed to safeguard people against hazards other than those concerned with nuclear radiation.

Optics and photonics

Optics and photonics* are “enabling technologies” that not only influence information technology, telecommunications, lighting and energy, but also have innovative applications in healthcare and life sciences through advanced laser technology and automation.

- **ISO/TC 172**, *Optics and photonics*

This health committee helps develop uniform terminology and test methods for handling safety issues properly.

* ISO standards in this field span a range of sectors from highly sophisticated systems down to “simple” semi-finished products or components, such as medical/surgical lasers, bar-code readers, sensors and other electro-optical instruments.



Medical devices

- **ISO/TC 210**, *Quality management and corresponding general aspects for medical devices*

This health committee focuses on the requirements and guidance in the field of quality management for medical devices.

- **ISO/TC 198**, *Sterilization of healthcare products*

This health committee lays down the requirements for sterilization processes, sterilizing equipment, washer-disinfectors and ancillary products used to ensure the satisfactory sterilization of healthcare products.

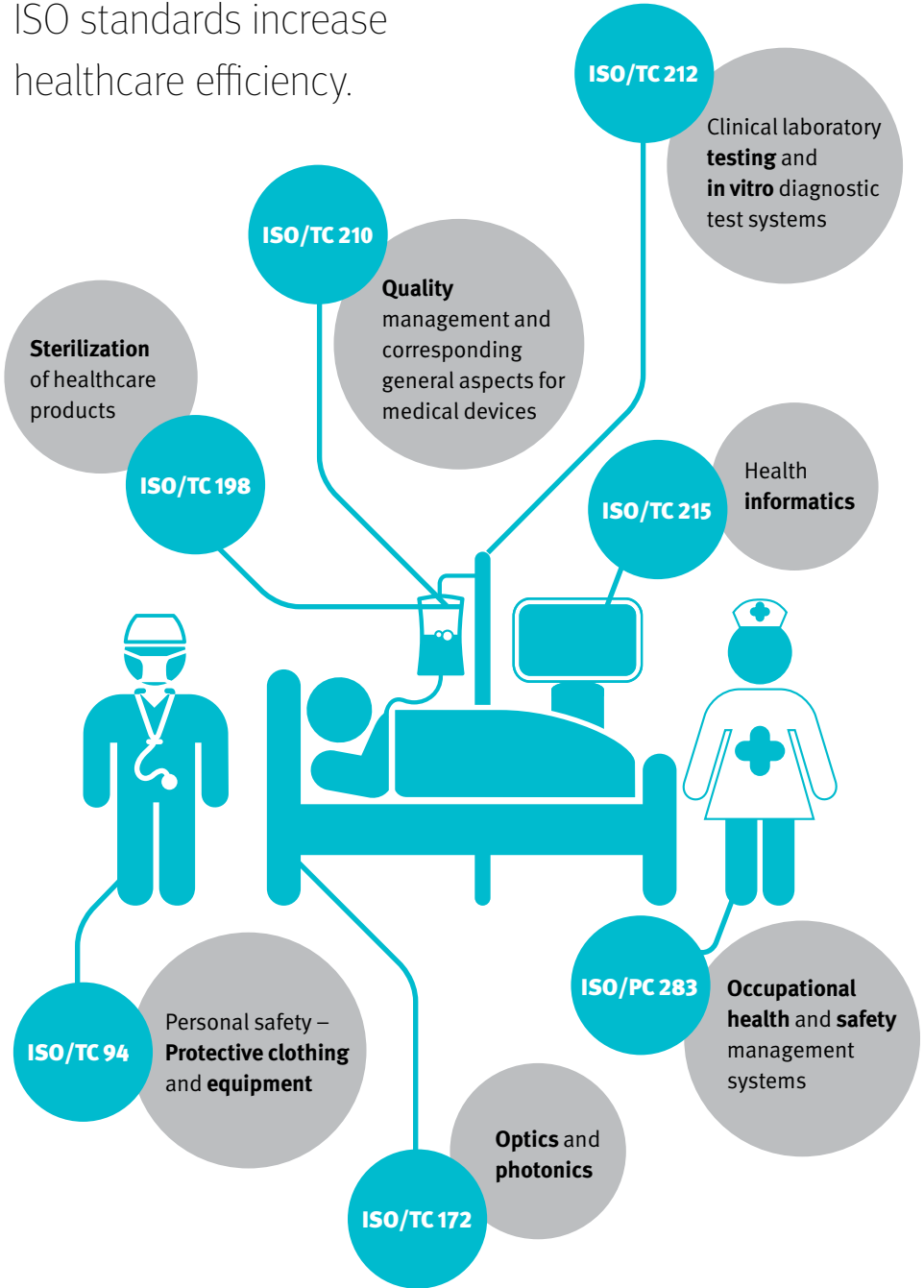
E-health technologies

The standardization of health informatics means that data can be collated more efficiently and shared more effectively.

- **ISO/TC 215**, *Health informatics*

This health committee strives to achieve compatibility and interoperability between independent systems in the use of health-related data, information and knowledge to support all aspects of the health system.

ISO standards increase healthcare efficiency.



Are there other ISO/TCs related to health?

- **ISO/TC 76**, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*
- **ISO/TC 84**, *Devices for administration of medicinal products and catheters*
- **ISO/TC 106**, *Dentistry*
- **ISO/TC 121**, *Anaesthetic and respiratory equipment*
- **ISO/TC 150**, *Implants for surgery*
- **ISO/TC 157**, *Non-systemic contraceptives and STI barrier prophylactics*
- **ISO/TC 168**, *Prosthetics and orthotics*
- **ISO/TC 170**, *Surgical instruments*
- **ISO/TC 173**, *Assistive products for persons with disability*
- **ISO/TC 181**, *Safety of toys*
- **ISO/TC 194**, *Biological and clinical evaluation of medical devices*
- **ISO/TC 215**, *Health informatics*
- **ISO/TC 249**, *Traditional Chinese medicine*

Get involved!



Would you like to have your say on the rules governing world trade?



Do you want to know which standards can benefit your business?



Do you have a good idea for a much needed standard?

**Contact the ISO member
in your country:**
www.iso.org/isomembers

More information?



ISO Website

www.iso.org



ISO Website section on health

www.iso.org/iso/health



ISOfocus magazine

www.iso.org/isofocus



ISO videos

www.iso.org/youtube



Follow us on Twitter

www.iso.org/twitter



Join us on Facebook

www.iso.org/facebook



Join us on GooglePlus

www.iso.org/gplus

**International
Organization
for Standardization**

ISO Central Secretariat
Chemin de Blandonnet 8
CP 401
1214 Vernier, Geneva
Switzerland

iso.org

© ISO, 2016
All rights reserved

ISBN 978-92-67-10661-8



The symbol on the cover comes from the International Standard **ISO 7000, *Graphical symbols for use on equipment – Registered symbols***. It is used on medical devices or blood process applications to indicate that the device or process application includes a system dedicated to the collection of samples of a given substance stored in this medical device or blood container.

Available on our Online Browsing Platform at gotol.iso.org/isosymbols.