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.

164* members

22 500*
International Standards

100
new standards each month

249*
technical committees

26*
technical meetings were in progress, on average, each working day of the year somewhere in the world

* March 2019

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.

More than 1400 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**

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.
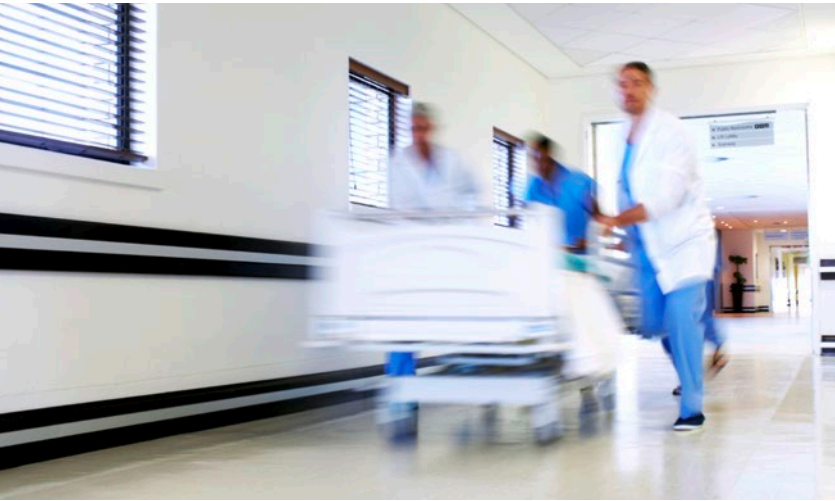
☐ Regulators

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

Optics

Equipment for transfusions

Infusions and injections

Medical devices

Surgery

Assistive products

Sterilization of healthcare products

Health informatics

Traditional Chinese medicine

Implants for surgery

Healthcare organization management

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 practices and products through proficient quality and risk management.

- **ISO/TC 210**, *Quality management and corresponding general aspects for medical devices*
This health committee develops standards for the application of risk management to the design and manufacture of medical devices. It also covers small-bore connectors used to connect medical devices, such as tubing, syringes and other accessories delivering fluids and gases for patient care.

- **ISO/TC 212**, *Clinical laboratory testing and in vitro diagnostic test systems*
This health committee provides a practical approach to reducing error in medical laboratories through risk management and continual improvement. Current standards cover laboratory safety, analytical performance and quality assurance. Future areas of focus include the management of biorisks, i.e. risks originating from the handling of biological agents and toxins.

Medical devices

- **ISO/TC 194,** *Biological and clinical evaluation of medical devices*

This ISO technical committee standardizes biological test methods for the evaluation of medical and dental materials and devices prior to their release for commercial use.

- **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.

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.

Oral health

• **ISO/TC 106,** *Dentistry*

A major sector in ISO is healthcare technology. Standardization in oral healthcare includes terminology, methods of test and specifications applicable to materials, instruments, appliances and equipment used in all branches of dentistry.

Surgical implants

• **ISO/TC 150,** *Implants for surgery*

This health committee sets out specifications and test methods for the safety and effectiveness of surgical implants that are inserted into the body for diagnostic or therapeutic purposes.

Healthcare organization management

Healthcare services management involves a lot of moving pieces, including health facilities, medical equipment, staff and patients. Good organization is essential to managing these multiple and interdependent functions.

- **ISO/TC 304**, *Healthcare organization management*
Drawing on best practice and advances in scientific research, this health committee develops standards for the classification, terminology, nomenclature, management practices and metrics covering non-clinical operations of healthcare entities. It is currently working on three standards covering the vocabulary of healthcare management (ISO 22886), hand hygiene practices (ISO 23447) and patient-centred staffing (ISO 22956).
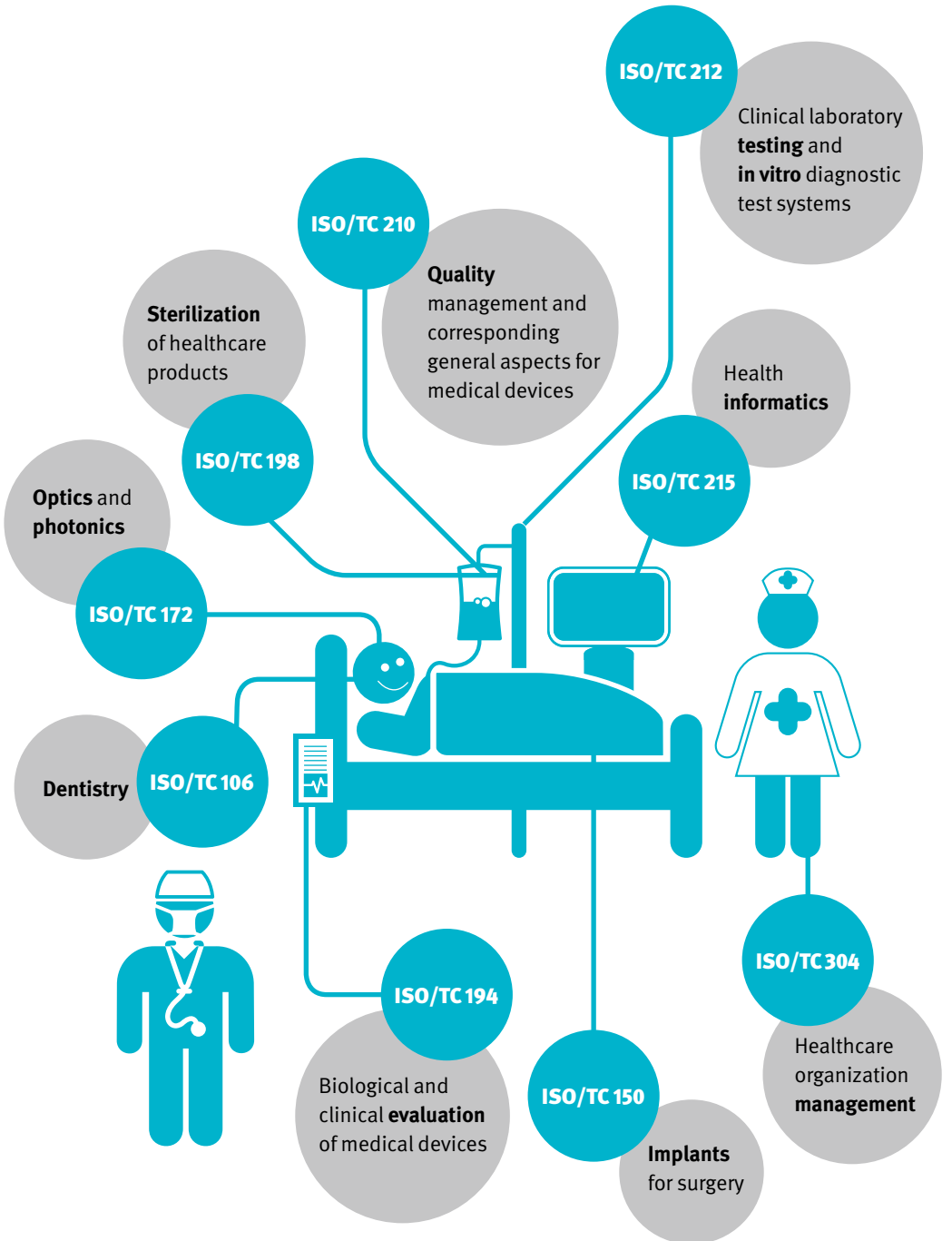
E-health technologies

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/TC 212
Clinical laboratory **testing** and **in vitro** diagnostic test systems

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

Sterilization of healthcare products

ISO/TC 198

Health **informatics**

ISO/TC 215

Optics and **photonics**

ISO/TC 172

Dentistry

ISO/TC 106

ISO/TC 194
Biological and clinical **evaluation** of medical devices

ISO/TC 150
Implants for surgery

ISO/TC 304
Healthcare organization **management**

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 94**, *Personal safety – Personal protective equipment*
- **ISO/TC 121**, *Anaesthetic and respiratory equipment*
- **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*
- **ISO/TC 181**, *Safety of toys*
- **ISO/TC 249**, *Traditional Chinese medicine*
- **ISO/TC 283**, *Occupational health and safety management*

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 : " standards in action "
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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 **gotoi.so/isosymbols**.