

DESIGN STANDARDS

After reading this fact sheet you should:

- Know what design standards are and understand the requirement for the standards in medical device development.
- Know how to find or access the design standards and have links to related resources.

Medical devices are subject to strict general controls and procedural regulations, and the development and use of standards is vital to ensuring the safety and efficacy of medical devices. Numerous regulatory agencies and standards organisations collaborate to establish the accepted standards for medical equipment. The type of device determines the agency (or agencies) to whose regulation it is subject. As a medical device innovator you should have some knowledge of design standards, even though it's a specialised field typically handled by design engineers and quality management systems experts.

What is a design standard?

A standard is an agreed way of making a product, managing a process, delivering a service or supplying materials. Standards can be agreed for all aspects of how we live, from standards for quality, product performance and safety to standards for building design and services.

Manufacturers (both domestic and foreign) and initial distributors (importers) of medical devices must register their establishments and list their medical devices with the regulatory agency of the country they wish to sell into. Listing of a medical device includes submission of the regulatory documents based on device classification along with submission of compliance towards design standards during the design, development and manufacturing of the device. You can get more detail on the US FDA regulatory pathway [HERE](#) and on US FDA compliance with design standards [HERE](#).

What types of standards are relevant to your medical device and why?

Knowledge of, and conformance to, standards recognised by the national regulatory body is key if you want your device to be approved for sale in a country. In Ireland, the **National Standards Authority of Ireland** develops standards through a consultative process. In the US, the **FDA** department responsible for regulating medical devices and radiation-emitting products, the **CDRH**, believes that conformance with recognised consensus standards can support a reasonable assurance of safety and/or effectiveness for many applicable aspects of medical devices.

A **database** containing the US FDA's recognised consensus standards from ≈25 standards organisations can be searched so you can find the relevant standards for your product. You can narrow your research by the Standards Organisation you wish to investigate.

Where can I buy or refer to standards?

The **National Standards Authority of Ireland** standards database includes the Indigenous Irish Standards (I.S.), the Adopted European Standards (I.S. EN; I.S. EN ISO/IEC), and the Adopted International Standards (I.S. ISO/IEC).

International Organisation for Standardization (ISO) is a non-governmental organisation that develops and publishes international standards on a wide range of subjects, including medical equipment. The **ISO 13485** standard establishes the requirements for a quality management system for both the design and manufacture of medical devices. It covers aspects including risk management, design control during product development, and verification and validation systems. You can search for ISO standards [HERE](#).

International Electrotechnical Commission (IEC) is a non-governmental organisation that prepares and publishes International Standards for all electrical, electronic and related technologies. The **IEC 60601** is a series of technical standards for the safety and effectiveness of medical electrical equipment. You can search through the IEC standards [HERE](#).

ASTM International (American Society for Testing and Materials) is a globally recognised leader in the development and delivery of international voluntary consensus standards. ASTM standards encompass virtually all medical devices and services imaginable – and all aspects relevant to medical devices, such as materials and biological components. ASTM standards encompass product areas including anaesthesia, biocompatibility, cardiovascular, dental, orthopaedics, plastic surgery, general surgery, general hospital devices (such as medical gloves), materials, neurosurgery, obstetrics and gynaecology, sterility in medical devices, and tissue engineering. You can search through the IEC standards [HERE](#).