

## Iso 14971 Wikipedia

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### Iso 14971 Wikipedia

ISO 13485 Medical devices -- Quality management systems -- Requirements for regulatory purposes is an International Organization for Standardization (ISO) standard published for the first time in 1996; it represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices.This standard supersedes earlier documents such as EN 46001 (1993 ...

### ISO 13485 - Wikipedia

ISO 15189 Medical laboratories — Requirements for quality and competence is an international standard that specifies the quality management system requirements particular to medical laboratories.The standard was developed by the International Organisation for Standardization's Technical Committee 212 (ISO/TC 212). ISO/TC 212 assigned ISO 15189 to a working group to prepare the standard based ...

### ISO 15189 - Wikipedia

The ISO 9000 family of quality management systems (QMS) is a set of standards that helps organizations ensure they meet customer and other stakeholder needs within statutory and regulatory requirements related to a product or service. ISO 9000 deals with the fundamentals of QMS, including the seven quality management principles that underlie the family of standards.

### ISO 9000 - Wikipedia

ISO 10303 is an ISO standard for the computer-interpretable representation and exchange of product manufacturing information.Its official title is: Automation systems and integration — Product data representation and exchange.It is known informally as "STEP", which stands for "STandard for the Exchange of Product model data".ISO 10303 can represent 3D objects in Computer-aided design (CAD ...

### ISO 10303 - Wikipedia

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