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13485:2003 & US FDA  
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Marketing medical  
devices at a global  
level can be a grueling  
and onerous task when  
trying to achieve  
compliance to various  
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compliance outlines  
Quality System  
Regulations for medical  
device

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The ISO 13485:2016  
standard details the  
changes between ISO  
13485:2003 and ISO  
13485:2016 in Annex A  
titled "Comparison of  
content between ISO

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13485:2003 and ISO  
13485:2016". Annex B  
of the standard is titled  
"Correspondence  
between ISO  
13485:2016 and ISO  
9001:2015" which  
details how those two  
standards relate to one  
another.

**Compare ISO  
13485:2016 to ISO  
13485:2003 to see  
what changed**

Compare ISO  
9001:2015 and ISO

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13485:2016 Quality Management Systems Structure. Although there are obvious differences within the structure of the standards, the overall requirements do not have as distinct of differences. The new structure was developed as a common structure for ISO standards, and to create terminology with simplified language.



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## **Compare ISO 9001:2015 and ISO 13485:2016: Integrating both QMS**

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Comparison of U.S. and  
EU device approval  
Approval of medical  
devices in both the EU  
and the United States  
share some similarities

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(Figure 2). The FDA assigns devices to 3 main regulatory classes: low risk or Class I, moderate risk or Class II, and high risk or Class III (Table 1).

### **Drugs and Devices: Comparison of European and U.S ...**

standards: the GHTF's Process Validation Guidance and the FDA's Process Validation: General Principles

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and Practices. These standards have considerable overlap, both officially and practically, across the drug and medical device industries. Previously, all FDA divisions followed a single guidance document, but that document has long since ...

**A Comparison of  
Process Validation  
Standards**

This paper provides

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comparison of the  
Safety and  
Performance  
Requirements (SPRs) of  
the new Medical  
Devices Regulation  
(MDR) and the  
Essential Requirements  
(ERs) of the Medical  
Devices and Active  
Implantable Devices  
Directives that they  
replace, allowing you  
to understand the  
changes in more detail.  
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## **Whitepapers and Articles | Medical Devices | BSI America**

<p>One common source of misunderstanding in the medical device industry is the method the various national regulatory systems use to identify standards. This article explains the method, starting with standards from the International

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Organization for  
Standardization (ISO)  
adopted and  
recognized in various  
regulatory systems.  
The article uses ISO  
13485:2003 and ISO  
14971:2007 as  
illustrations.</p>

### **An Introduction To International Medical Device Standards**

Part 803). Medical  
devices are divided  
into Class I, Class II and

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Class III where class I devices represent the lowest risk and class III devices represent the highest risk. Most Class I devices and some Class II devices are exempt from a Premarket Notification 510 (k). Class II devices generally require a 510 (k) while Class III

### **Global Regulatory Requirements for Medical Devices**

Sterilization of Medical



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Device- Validation and  
routine control of  
sterilization by  
irradiation . 7. EN554 .  
Sterilization of Medical  
Device by Moist Heat;  
8. EN556 ; Sterilization  
of Medical Device -  
Requirement for  
terminally-sterilized  
devices to be labeled  
Sterile polyurethane  
thermal insulation and  
outer casing of  
polyethylene. 9. EN556  
...

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## **LIST OF INTERNATIONAL STANDARDS FOR MEDICAL DEVICES NO ...**

Learn about the international material testing standards for medical devices and find out which standards apply to your products.

## **International-Testin g-Standards-for- Medical-Devices**

The US Food and Drug

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Administration (FDA)  
Standards  
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has announced  
changes to the list of  
recognized standards  
the agency uses in the  
medical device  
regulatory  
process. Manufacturers  
should familiarize  
themselves with the  
revised FDA list in  
order to issue accurate  
Declarations of  
Conformity and ensure  
compliance with these  
standards as part of  
their US medical device

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registration efforts.

## **US FDA list of recognized standards for medical devices**

Identifying the Correct  
FDA Guidance  
Documents and  
Standards. Clients who  
engage us for FDA  
510(k) submission  
consulting often ask  
what testing is  
required by the FDA to  
clear their device.

While testing

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requirements are easy to determine for some devices, other devices require intensive research.

### **Medical Device Testing Requirements for 510(k) Submissions**

...

This is a comparison of standards of mobile phones. ...

Manufacturers are often hesitant to release IS-95 devices

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due to the smaller market, so features are sometimes late in coming to IS-95 devices. Even barring subsidy locks, CDMA phones are linked by ESN to a specific network, ...

## **Comparison of mobile phone standards - Wikipedia**

The Medical Devices Regulations require class II, III and IV

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medical devices to be manufactured (class II) or designed and manufactured (class III & IV) under CAN/CSA ISO 13485:2003. There are no regulatory quality system requirements for Class I medical devices.

These quality system requirements came into force on January 1, 2003. Forms

**Quality Systems ISO  
13485 - Canada.ca**

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Topics will include comparison of CE Marking requirements vs. US FDA requirements, the new medical device regulations, classification of devices, clinical evaluation, use of standards and the new General Data Protection Regulation (GDPR).

## **CE Marking Medical Devices: The**



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## Comparison Of Medical Device Process, Part 1 - EU vs...

- Medical Device Reporting of adverse events as identified by the user, manufacturer and/or distributor of the medical device. Special Controls may include:
- Adherence to performance standards, guidance documents,
- Implementation of post-marketing surveillance measures,
- Special labelling.

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## **Standards Pharmaceutical Regulatory Affairs: a I ...**

The use of standards is voluntary, except in those particular cases where certain standards have been deemed mandatory by the Regulatory Authority.

Manufacturers should be free to select alternative solutions to demonstrate their

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medical device meets  
the relevant Essential  
Principle.

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