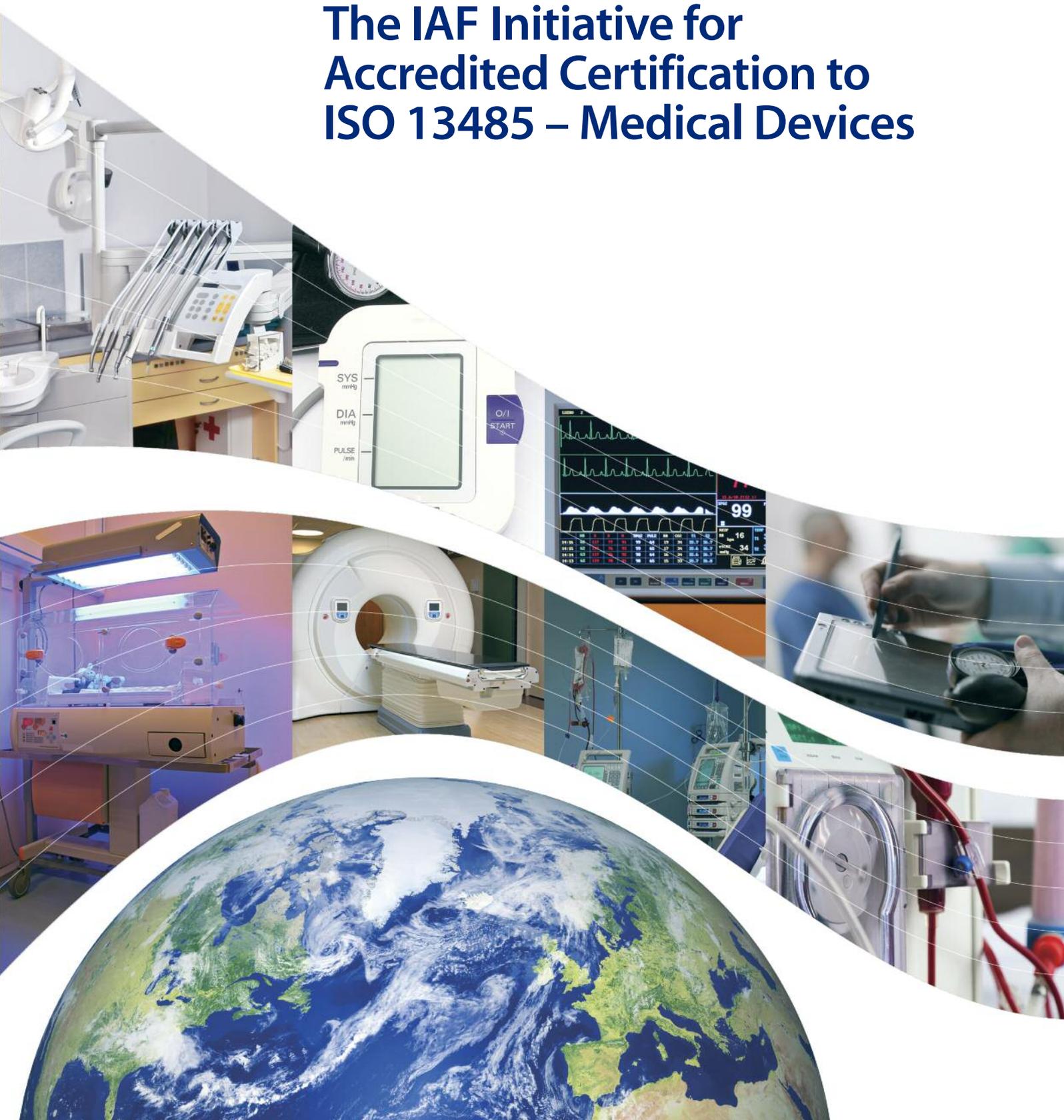




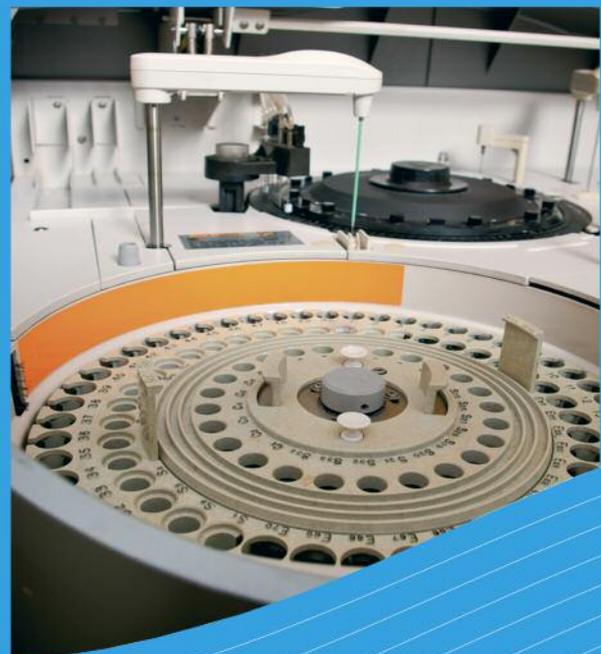
**Certified Once
Accepted Everywhere**

The IAF Initiative for Accredited Certification to ISO 13485 – Medical Devices



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Introduction

The purpose of this brochure is to explain the benefits and use of the ISO 13485 Medical Device initiative developed by the International Accreditation Forum (IAF).

The initiative enables IAF accredited certification bodies to provide consistent, credible certification to ISO 13485. The documents, developed as part of the IAF initiative, which are mandatory to both accreditation bodies within IAF and all certification bodies accredited by them to provide certification to ISO 13485, also enable national authorities with an opportunity to enhance their healthcare systems through the implementation of accredited ISO 13485 certification, without losing valuable access to medical devices that they are already using.

This brochure describes the importance of accredited certification and the roles and responsibilities of the different stakeholders with an interest in this scheme. It explains the context within which ISO 13485 accredited certification is expected to be used and the links between this and medical device trade and public health.

This informative guidance is intended to help the understanding of the utilisation of ISO 13485 accredited certification.

Objectives of the Initiative

- Application of the initiative enables IAF accredited certification bodies to provide consistent, credible certification to ISO 13485.
- The initiative documents, which are mandatory to both accreditation bodies within IAF and all certification bodies accredited by them to provide certification to ISO 13485.
- To enable national authorities with an opportunity to enhance their healthcare systems through the implementation of accredited ISO 13485 certification, without losing valuable access to medical devices.



ISO 13485 accredited certification within a national regulatory framework

Granting healthcare practitioners access to medical devices that are made in another country is critical to all healthcare systems. Indeed, most countries import more medical devices than they export. Each country must sensibly regulate access to medical devices in order to protect their citizens from unsafe devices.

Regulators are increasingly realizing the benefit of recognizing the quality management system standard ISO 13485 – Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes. This international standard provides the basis for medical device regulations to be harmonized around the world.

Just as doctors and patients benefit from receiving medical devices made outside their country, medical device industries throughout the world benefit from being able to provide them. In 2011, there were 6.5 billion people in the world living in 192 countries. Many of these countries do not have harmonized medical device regulations to protect their citizens, yet the need to protect their citizens is great. As each nation develops its own national medical device regulations, the likely increased demand for national factory audits would become impossible to bear for a manufacturer. This would not merely result in a barrier to trade for the supplier, but also a barrier to care for the importing country. Many countries import more than 90% of their healthcare technologies. By utilizing the international standard ISO 13485, with cooperation of IAF member accreditation bodies, the medical device industry can be provided with one ISO 13485 certificate that can be accepted everywhere, while also meeting the importing countries demand for safe and effective medical devices.

Use of this initiative very much depends upon awareness among the global regulatory community. In particular, organizations such as the Global Harmonization Task Force (GHTF), Pan American Health Organization (PAHO), Asian Harmonization Working Party (AHWP) and Association of Southeast Asian Nations (ASEAN) are very important to the harmonization of medical device regulations. However, even with the endorsement of such organizations, it is equally important that individual regulatory authorities are aware of the requirements and structure of this initiative.

ISO 13485 is intended to address medical device regulatory requirements for a quality management system. Although ISO 13485 is based on the Quality Management Systems standard ISO 9001, it focuses less on business performance and more on risk management. ISO 13485 ensures that medical device manufacturers consistently produce medical devices that meet regulatory requirements and are designed and manufactured to be safe for their intended use.

Many international regulators have directly or indirectly endorsed use of ISO 13485 as the model for meeting their own regulatory requirements for medical device manufacturing. Many countries have developed their medical device regulations using ISO 13485 or the criteria within it, and other countries are now using or beginning to use this same standard in their medical device regulations.



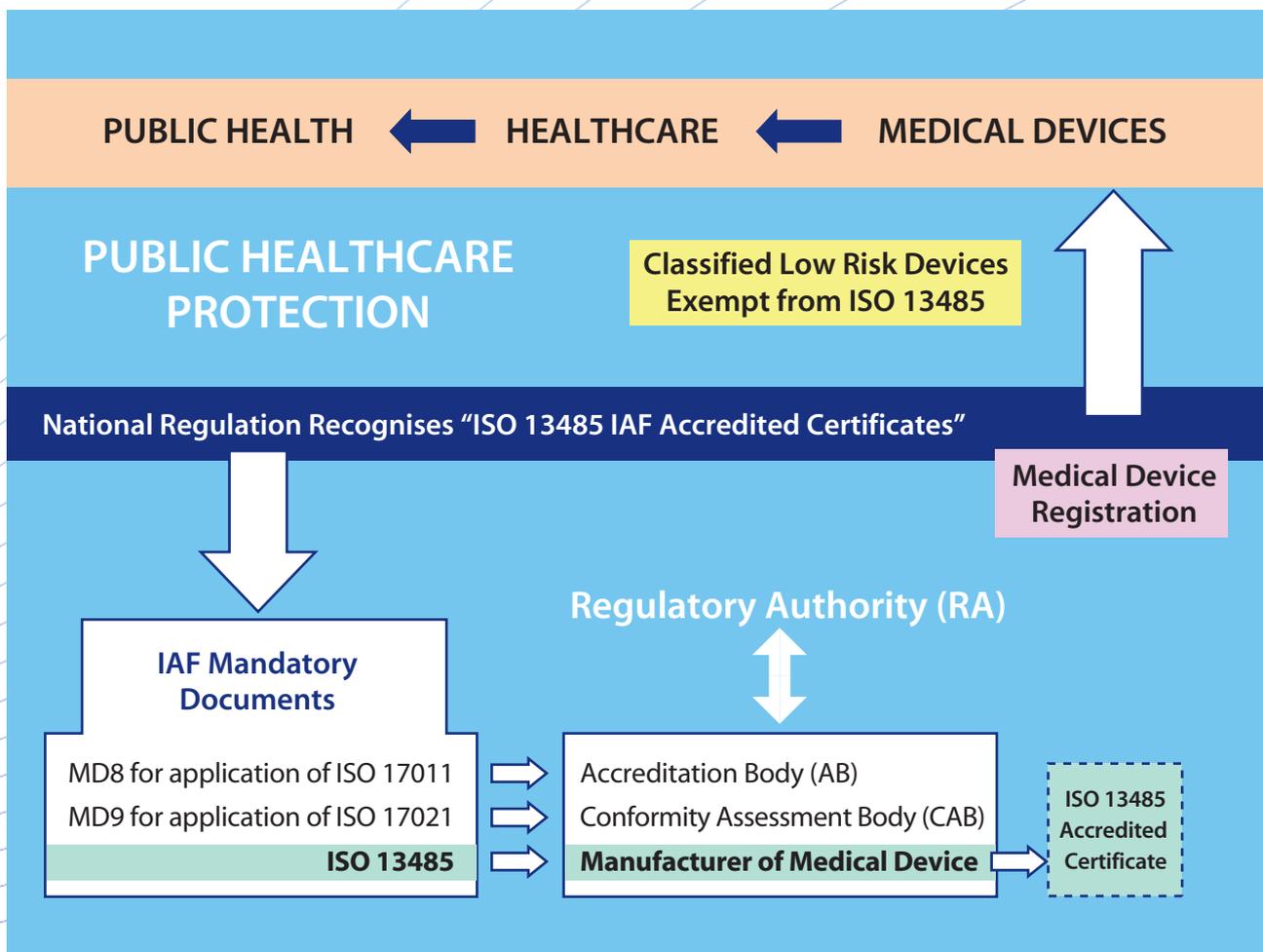
Medical device regulators, certification bodies and members of GHTF have worked together to provide a common framework for regulating medical devices. GHTF Study Group 3 has created several documents that provide helpful guidance on the application and interpretation of ISO 13485. GHTF Study Group 4 provides guidance on the methodologies and requirements for the audit of quality systems against ISO 13485.

The IAF initiative enables consistent and credible ISO 13485 certification. Without the harmonization

provided by IAF, there remains the potential for variations of credibility among issued ISO 13485 certificates.

The IAF documents were created to be used for developing and improving medical device regulations around the world, while preventing unnecessary barriers to care at the national level.

A summary of the relationships between key stakeholders is shown in the following diagram:



Relationship to guidance from the Global Harmonization Task Force (GHTF)

The IAF ISO 13485 medical devices initiative has been optimized using GHTF guidance. For many years, GHTF members have strived to create a system of documents that can form the basis for medical device regulatory programs worldwide.

The IAF initiative utilizes GHTF guidance from Study Group 4 concerning regulatory auditing practices. The initiative incorporates this guidance to support an infrastructure that links regulatory authorities, accreditation bodies, certification bodies, and medical device manufacturers.

The IAF initiative for ISO 13485 does not require use of any additional GHTF documents. IAF accredited certification does however support regulations that incorporate other GHTF guidance. If GHTF guidance is to be used in forming a new medical device regulation, the following uses of GHTF guidance should be considered.

Guidance documents from GHTF Study Groups 1, 2, 3, and 5 describe core concepts for developing a harmonized medical device regulatory system. Regulators may reference such documents for use as criteria that manufacturers must follow or they may adopt the language directly into national law. GHTF Study Group 4's guidance relevant to IAF ISO 13485 accredited certification has already been included in the IAF Mandatory Document for the application of ISO/IEC 17021 (IAF MD9).

Regulatory bodies may not want or be able to fully implement all documents and requirements of the GHTF due to particular local or national concerns.

Therefore regulators should make the medical device industry aware of any national deviations from the GHTF approach that could possibly cause manufacturers delays in compliance. It is also very important to consider the restrictions on legal access to medical devices that may result from imposing deviations.

***Note:** Whilst the long-term future of the GHTF is not certain, as at 2011 the view of achieving harmonised regulatory requirements remains a highly desirable objective, particularly in view of the pressures of a globalised manufacturing market for medical devices and increasing demands to streamline regulatory processes in order to deliver high quality products to the marketplace with minimal delays. The GHTF regulator's group considered that the best way to achieve such an outcome was to develop a regulator-led harmonisation and collaboration group that would allow for more detailed discussion between members on the optimum ways to achieve harmonisation at an operational level. The strategy of achieving this, together with adequate input and advice from industry, was still under consideration in mid-2011..*

How ISO 13485 certification relates to product certification

Although an audit performed under the ISO 13485 may include an examination of a product's design and development, ISO 13485 is not a product certification standard. The certification based on ISO 13485 is not directly linked to the specification of the manufactured products. ISO 13485 certification indicates that the processes for designing and manufacturing medical devices are appropriate for providing consistent product quality and safety.



The IAF Multilateral Recognition Arrangement (MLA)

IAF is an organization of accreditation bodies and other interested stakeholders from more than 50 countries. Most accreditation bodies operate under the authority of their own nation's government and cooperate in the development and maintenance of Multilateral Recognition Arrangements (MLAs). Signatories to the IAF MLA agree to promote acceptance of accredited certificates issued by all the other IAF MLA signatories within the scope of the MLA. Thus the MLA underpins the recognition of ISO 13485 certificates issued by certification bodies accredited by IAF member accreditation bodies.

Structure of the MLA

Certificates issued by bodies accredited by the IAF MLA Signatories can be relied upon throughout the world because the MLA assures the credibility of the certificate to customers.

The MLA is structured in 5 levels. ISO 13485 fits into these levels as follows:

Level 1 – Includes ISO/IEC 17011 and the IAF Mandatory document (MD8) on the application of ISO/IEC 17011 in Medical Device Quality Management Systems (ISO 13485);

Level 2 – Describes the type of conformity assessment activity e.g. Management Systems. The IAF accreditation system for ISO 13485 will form part of management system activities (no additional documentation required);

Level 3 – ISO/IEC 17021;

Level 4 – The sector specific requirements have been developed by the IAF Technical Committee and are contained in the IAF mandatory document (MD 9) on the

application of ISO/IEC 17021 for the Medical Device Quality Management Systems (ISO 13485).

Level 5 – ISO 13485.

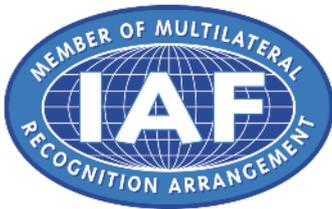
Accreditation bodies that are signatories to the IAF MLA may extend their scope of operation to include medical devices if they accredit certification bodies that issue ISO 13485 certificates. They will do this either directly to IAF or through their regional group if the regional group includes ISO 13485 as part of their regional MLA.



IAF MLA Mark

The documentation has been developed to ensure that the initiative gains as much advantage from the IAF MLA as possible by ensuring that accredited certificates issued to ISO 13485 are able to include the IAF MLA Mark, which is the IAF MLA Mark in combination with the symbol of the accreditation body. The IAF MLA Mark will not appear on certificates on its own.

The IAF MLA mark's appearance on an ISO 13485 Certificate assures the user of the certificate that the ISO 13485 audit is highly credible and operating under IAF MLA Management.



The Mark demonstrates that the certificate has been issued by a certification body that is accredited by an IAF MLA member and is thus traceable to the highest authority. It is an assurance that the certificate and the issuing body are of a high standard of competence and may be trusted, as they are recognised as complying to the same set of standards at the global level.

To ensure that the IAF MLA Mark may be used on accredited certificates, the initiative has been endorsed by the IAF in accordance with the document IAF PL3.

The IAF MLA mark can be used by accreditation bodies to demonstrate their status as a signatory to the IAF MLA. Accredited certification bodies can also use the mark in combination with the accreditation symbol on their certificates providing they are issued in association with IAF endorsed normative documents such as ISO 13485.



Key Features of the Initiative



The relationship of Risk Classification of Medical Devices to QMS requirements

The significance of risk classification to the QMS is that based on whether the medical device is higher or lower risk, the regulator may or may not require the manufacturer’s quality management system to be independently certified to ISO 13485. The purpose of classification is to match regulatory oversight and market clearance to the level of risk of the device’s risk.

Lower risk medical devices usually do not require independent certification of the manufacturer’s QMS.

The illustration below is a very basic example of how ISO 13485 certification could be applied to four different risk classifications for medical devices:

Manufacturer’s Obligations to a Quality Management System				
Medical Device Risk Classification	GHTF Risk Class	IAF accredited certification to ISO 13485 Not Required	IAF accredited certification to ISO 13485 Required	IAF accredited certification to ISO 13485 Including Design and Development Controls
High Risk	D			x
Medium-high Risk	C			x
Medium-low Risk	B		x	
Low Risk	A	x*		

*Low risk medical devices are exempt from ISO 13485 Certification



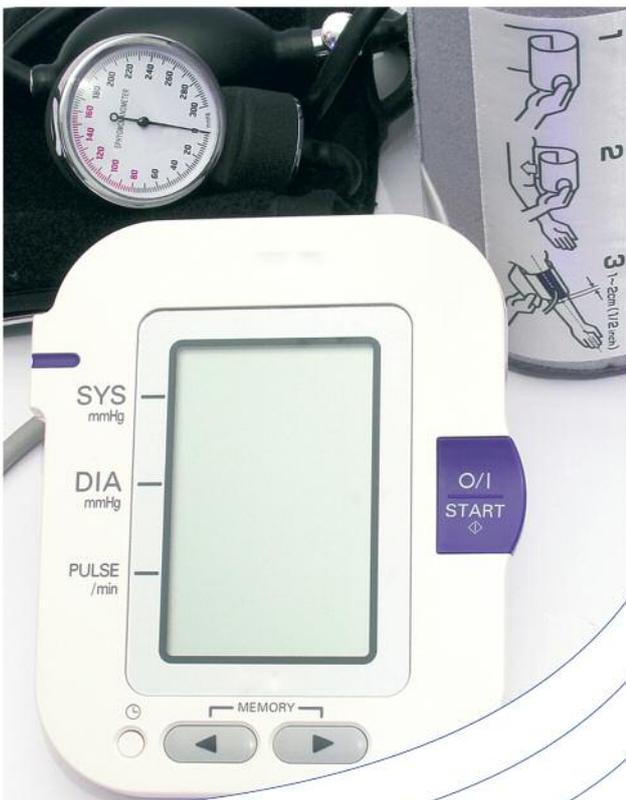
Two approaches to that are widely used to determine risk classification:

Risk classification rules

Risk “classification rules” use general principles of risk, related to patient contact with energy, substances, invasiveness into the body, as well as other criteria, to determine the risk level of a medical device. Higher risk devices have a contact with the body for a longer time period than lower risk devices. They are more invasive inside the body or rely on a more hazardous energy sources. Several risk rules can be found to apply to one medical device. It is the responsibility of the manufacturer to apply the higher risk classification when more than one risk classification is identified using applicable risk rules. A full list of risk classification rules can be viewed in the GHTF document SG1-N15: 2006 – “Principles of Medical Devices Classification.”

Risk classification names

Risk classification names appear as an assigned risk classification next to the name of the medical device type (e.g. Blood Pressure Cuff – Class B). The Medical Devices risk classifications are then made public and allow the regulatory authority to adjust the risk classification more easily, if post market experience shows a particular product to be more, or less safe than originally thought. Changing a risk classification for one product, does not change the risk classification of another. Risk classifications may be assigned by consensus from a group of medical device experts. Some medical device experts use risk classification rules to assign the first risk classification for a new type of medical device.



Although the IAF initiative for ISO 13485 does not prescribe any risk classification system, requirements for ISO 13485 certification should be based on the risk of a device to public health.

Reports associated with the IAF Initiative

Reports exist on how the participants at the different layers within the IAF ISO 13485 certification initiative meet the particular requirements that are appropriate for them:

Accreditation body peer evaluation report

Under the IAF MLA, a peer evaluation report covers the accreditation body's performance in meeting, among other things, the IAF Mandatory Document for the application of ISO/IEC 17011 – Conformity Assessment – *General Requirements for Accreditation Bodies Accrediting Certification Bodies in the Medical Device Quality Management Systems (ISO 13485)*.

Assessment report on the certification body

Under the accreditation for ISO 13485 by IAF accreditation body members, the accreditation body provides an accreditation assessment report of a certification body's performance in meeting, among other things, the IAF Mandatory Document for the application of ISO/IEC 17021 – Conformity Assessment – *Requirements for Bodies Providing Audit and Certification of Management Systems in the Medical Device Quality Management Systems (ISO 13485)*.

Medical device manufacturer's audit report

This is the audit report prepared by the certification body that indicates the medical device manufacturer's performance in meeting, among other things, the requirements of the quality management system standard ISO 13485.

Regulatory authorities that have specified the use of the IAF accredited ISO 13485 certification initiative in their legislation may be provided access to the accreditation body, certification body and the participating medical device manufacturer's reports and facilities.



Using Accredited ISO 13485 Certification in Practice

Practical Aspects of Specifying IAF Accredited ISO 13485 Certificates in Medical Device Regulations

Requirements for IAF accredited certification are designed to enforce one credible and transparent ISO 13485 audit to meet the needs of regulatory authorities. In order for this to occur, ISO 13485 certificates should be identified in the national medical device regulation through appropriate national legislative processes.

By recognizing IAF accredited ISO 13485 certificates in the national legislation, countries gain access to the audit reports in addition to being able to inspect any participating accreditation body, certification body or medical device manufacturer. Although there are many ways in which ISO 13485 accredited certificates may be included into a new medical device regulation, the most likely approach would be to specify it as a requirement for registering medium risk or higher risk medical devices with the Regulatory Authority.



An example of how a national medical device regulation could reference IAF accredited ISO 13485 certificates is provided below.

The use of the IAF accredited ISO 13485 certification program can make a significant contribution towards developing a harmonized medical device regulation. It does not, however, describe or mention Medical Device Reporting (MDR), how to classify the risk level of a medical device or how they should be labelled. IAF accredited ISO 13485 certificates are expected to be part of the medical device regulation that pertains to product registration and quality management system requirements. The GHTF provides free, detailed guidance at www.gh tf.org for developing a more complete and harmonized medical device regulation.

[Regulation Number] Medical Device Registration

An application for registering a class 2 or higher medical device shall be submitted to the [Name of Regulatory Authority] by the manufacturer and shall contain the following:

- a) A copy of a current and valid IAF accredited ISO 13485 quality management system certificate certifying that the quality management system under which the device is manufactured satisfies ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes.
- b) ...other requirement(s)

Using Accredited ISO 13485 Certification in Practice *continued*

Considering exemptions for ISO 13485 certification

In 2011, there are an estimated 5,000 different medical device categories that account for 90,000 different products used by healthcare systems worldwide. More than 50% of these medical devices are considered low risk. Many low risk medical devices are safer than less regulated consumer products.

Allowing healthcare professionals access to a wider range of medical devices provides a necessary benefit to a country's healthcare system. Accredited ISO 13485 certification is suggested for regulating medium to high risk medical devices.

Transition period for requiring IAF accredited ISO 13485 certificates

Although it is expected that accredited certificates for ISO 13485 will become available within the first year of its adoption by IAF, regulators need to provide manufacturers with an opportunity to learn and adapt to any new regulation. Enforcing IAF accredited certification before industry has had time to prepare could have an adverse impact on the healthcare system if it is enforced too soon. Each country that

adopts the IAF accredited certification to ISO 13485 into its regulations should make the new regulation as widely known as possible to provide medical device manufacturers time to prepare. It is recommended that a transition period of three years be provided to allow all stakeholders time to adjust to the IAF accreditation requirements.

Communication between Stakeholders

In order for this IAF accredited ISO 13485 Certification Initiative to contribute to an efficient regulatory system, it is vital for effective communication channels to exist between regulators, accreditation bodies and conformity assessment bodies. Communication is a key element of this initiative and is intended to support mutual confidence building.

It is recommended that regulators establish a communication framework between them and their local accreditation body that is visible to the conformity assessment bodies and medical device manufacturers.





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