IAF Informative Document

IAF Medical Device Nomenclature (IAF MDN) Including Medical Device Risk Classifications

Issue 1, Version 2

(IAF ID 13:2023)

Issued: 13 June 2023 Application Date: 30 January 2017 IAF ID 13:2023
Issue 1, Version 2

The International Accreditation Forum, Inc. (IAF) facilitates trade and supports industry and regulators by operating a worldwide mutual recognition arrangement among Accreditation Bodies (ABs) in order that the results issued by Conformity Assessment Bodies (CABs) accredited by IAF members can be accepted globally.

Accreditation reduces risk for business and its customers by assuring them that accredited CABs are competent to carry out the work they undertake within their scope of accreditation. ABs that are members of IAF and their accredited CABs are required to comply with appropriate international standards and IAF mandatory documents for the consistent application of those standards.

ABs that are signatories to the IAF Multilateral Recognition Arrangement (MLA) are evaluated regularly by an appointed team of peers to provide confidence in the operation of their accreditation programs. The structure of the IAF MLA is detailed in IAF PL 3 - Policies and Procedures on the IAF MLA Structure and for Expansion of the Scope of the IAF MLA. The scope of the IAF MLA is detailed in the IAF MLA Status document.

The IAF MLA is structured in five levels: Level 1 specifies mandatory criteria that apply to all ABs, ISO/IEC 17011. The combination of a Level 2 activity(ies) and the corresponding Level 3 normative document(s) is called the main scope of the MLA, and the combination of Level 4 (if applicable) and Level 5 relevant normative documents is called a sub-scope of the MLA.

- The main scope of the MLA includes activities e.g. product certification and associated mandated standards e.g. ISO/IEC 17065. The attestations made by CABs at the main scope level are considered to be equally reliable.

- The sub scope of the MLA includes conformity assessment requirements e.g. ISO 9001 and scheme specific requirements, where applicable, e.g. ISO 22003-1. The attestations made by CABs at the sub scope level are considered to be equivalent.

The IAF MLA delivers the confidence needed for market acceptance of conformity assessment outcomes. An attestation issued, within the scope of the IAF MLA, by a body that is accredited by an IAF MLA signatory AB can be recognized worldwide, thereby facilitating international trade.

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Approved by: IAF Members Date: 16 December 2016
Issue Date: 13 June 2023 Application Date: 30 January 2017
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INTRODUCTION TO IAF INFORMATIVE DOCUMENTS

This IAF Informative Document reflects the consensus of IAF members on this subject and is intended to support the consistent application of requirements. However, being a document for information purposes only, IAF Accreditation Body Members, and the Conformity Assessment Bodies they accredit, are not under any obligation to use or comply with anything in this document.

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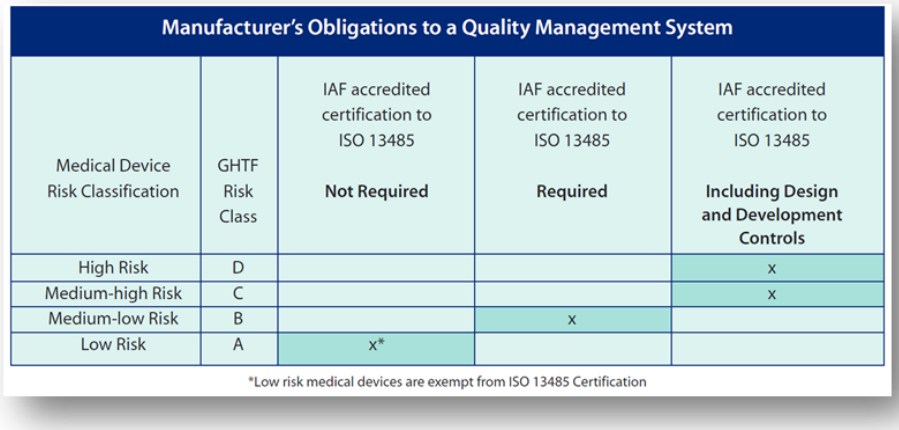
1. INTRODUCTION

This IAF Medical Device Nomenclature document (IAF MDN) is an informative document that was developed for the support of IAF MD8 and MD9. It provides long established medical device names and classifications, where risk classifications do not exist in the Global Medical Device Nomenclature (GMDN).

Within this guide, there are more than 6,000 specific medical device names, divided into 16 categories. The IAF MDN is useful to Accreditation Bodies (ABs) and Conformity Assessment Bodies (CABs), as well as those preparing for an audit or accreditation assessment.

IAF MDN includes multiple risk classifications to help provide a general view of the level of risk of a device. The IAF MDN is clearly an informative document, and is not to be used for determining risk classification for regulatory purposes.



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

Illustration from the IAF Initiative for Accredited Certification to ISO 13485 – Medical Devices

2. SCOPE

The scope of the document in relation to: (1) its relationship to ISO 13485 and conformity assessment requirements, (2) IAF MDN content- product names, risk classification assignments, implant, life-sustaining/supporting devices and regulatory use is outlined below.

2.1 Relationship to ISO 13485 and Conformity Assessment Requirements

ISO 13485:2016 is more focused on minimizing medical device risks than any of its preceding revisions. The IAF MDN provides a naming convention and various risk classifications for sharing, communicating, and exchanging information related to most medical devices in circulation worldwide.

The relationships of Risk Class to Conformity Assessment requirements relating to ISO 13485 are set forth in some of the medical device regulations included by reference in the following pages. Unclassified devices are indicated with the letter "U". Above is an illustration that shows a common approach to using ISO 13485, including requirements for Design and Development Controls for higher risk medical devices, and exemptions for lower risk medical devices.

2.2 IAF MDN Content

2.2.1 Product Names

The IAF MDN uses names derived from US FDA Product Codes. These medical device names have been established through decades of use worldwide and were compiled here for their clearest association with a risk classification and their ability to provide a more suitable instrument for further self-study of medical devices and their specific risks.

2.2.2 Risk Classification Assignments

The risk classifications were assigned according to risk rules used in the Global Harmonization Task Force document GHTF/SG1/N77:2012, risk rules indicated in Canadian Regulation SOR98-282 Schedule 1, and the European Medical Device Directive 93/42/EEC Annex IX. All risk classifications from the US FDA were derived from association with medical device “Classification Names” under Part 800 of the US Code of Federal Regulation.

2.2.3 Implant, Life Sustaining/Supporting Devices

Devices that are implanted in the body long term, or devices considered to be Life Sustaining or Life Supporting, are indicated as Y (Yes) and N (No) where known to be related to the device name. These additional identifiers enhance understanding of the area or level of concern related to each device. Implanted, Life Sustaining/Supporting devices often require more risk management within the Quality Management Systems required by ISO 13485.

2.3 Disclaimer – Do not Use This Document for Regulatory Purposes

The IAF MDN is a tool for research and must not be used to meet regulatory purposes as a stand-alone source of information. This document is not to be used by itself to ascertain the risk classification of any medical device for regulatory purposes.

For further information on risk classification, it is recommended that users consider the most current medical device regulations affecting risk classification, and the Final Guidance Document GHTF/SG1/N77:2012 - Principles of Medical Devices Classification.

Risk classifications may vary between regions and economies. It is imperative that each medical device manufacturer use the current medical device regulations adopted within the jurisdictions into which they sell their product, to assure confidence in meeting the regulatory obligations for the markets where they operate.

3. REFERENCES

Canadian Medical Device Regulation SOR 98-282 (Schedule 1)

European Medical Device Directive 93/42/EEC (Annex IX)

GHTF Guidance document SG1-N77

US FDA database

4. MEDICAL DEVICE NOMENCLATURE - INDICATORS OF RISK CLASSIFICATION LEVEL

Risk classification levels are indicated in the IAF MDN with regard to Canadian, European, GHTF Guidance, and US FDA rules are as follows:

	Canada	Europe	GHTF	USA
Low Risk	1	1	A	1
Medium Low Risk	2	2a	B	2
Medium High Risk	3	2b	C	
High Risk	4	3	D	3

End of IAF Informative Document - IAF Medical Device Nomenclature (IAF MDN) Including Medical Device Risk Classifications.

Further Information

For further Information on this document or other IAF documents, contact any member of IAF or the IAF Secretariat.

For contact details of members of IAF see the IAF website: http://www.iaf.nu.

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