Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

Medical Device Regulatory Convergence Project (MDRC)

Good Regulatory Practices & Technical Competencies

South Africa Health Products Regulatory Authority (SAPHRA) & Regulated Sector

Augusto Geyer
Medical Devices Office
Brazilian Health Regulatory Agency

Pretoria, 15 November 2023

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Agência Nacional de Vigilância Sanitária

Essential Principles of Safety and Performance

GHTF/SG1/N68:2012

GHTF

FINAL DOCUMENT

Global Harmonization Task Force
(revision of GHTF/SG1/N41:2005)

Title: Essential Principles of Safety and Performance of Medical Devices

Authoring Group: Study Group 1 of the Global Harmonization Task Force

Date: November 2nd, 2012

Dr. Kazunari Asanuma, GHTF Chair

This document was produced by the Global Harmonization Task Force, a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia.

The document is intended to provide non-binding guidance to regulatory authorities for use in the regulation of medical devices, and has been subject to consultation throughout its development.

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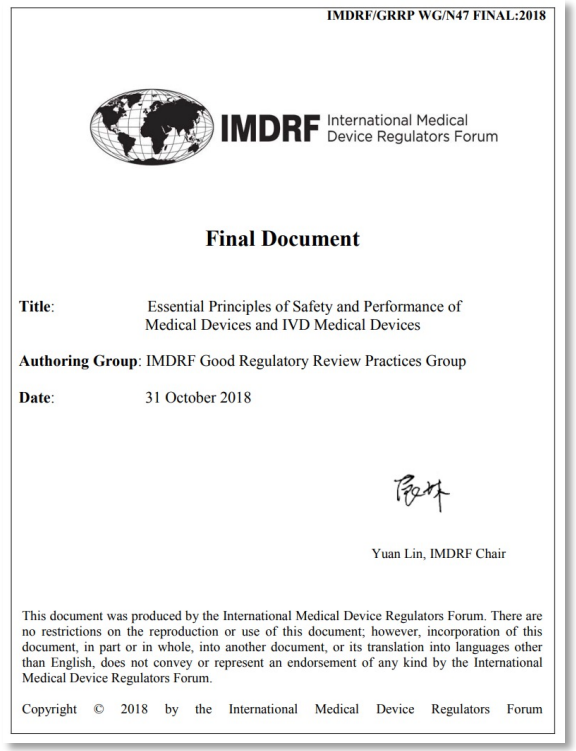

IMDRF/GRRP WG/N47 FINAL:2018

IMDRF International Medical Device Regulators Forum

Final Document

Title: Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

Authoring Group: IMDRF Good Regulatory Review Practices Group

Date: 31 October 2018

Yuan Lin, IMDRF Chair

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Participation of Anvisa in the IMDRF Working Groups since its foundation

IMDRF Good Regulatory Review Practices Working Group

Development of the technical document based on GHTF/SG1/N68:2012 (revision of GHTF/SG1/N41:2005)

IMDRF/GRRP WG/N47 FINAL:2018

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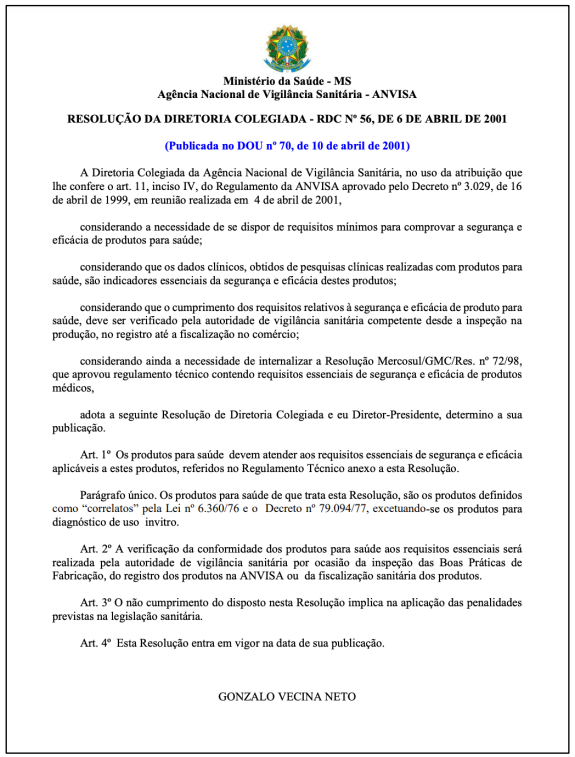
Essential Principles of Safety and Performance



Ministério da Saúde - MS
Agência Nacional de Vigilância Sanitária - ANVISA

RESOLUÇÃO DA DIRETORIA COLEGIADA - RDC Nº 56, DE 6 DE ABRIL DE 2001

(Publicada no DOU nº 70, de 10 de abril de 2001)

A Diretoria Colegiada da Agência Nacional de Vigilância Sanitária, no uso da atribuição que lhe confere o art. 11, inciso IV, do Regulamento da ANVISA aprovado pelo Decreto nº 3.029, de 16 de abril de 1999, em reunião realizada em 4 de abril de 2001,

considerando a necessidade de se dispor de requisitos mínimos para comprovar a segurança e eficácia de produtos para saúde;

considerando que os dados clínicos, obtidos de pesquisas clínicas realizadas com produtos para saúde, são indicadores essenciais da segurança e eficácia destes produtos;

considerando que o cumprimento dos requisitos relativos à segurança e eficácia de produto para saúde, deve ser verificado pela autoridade de vigilância sanitária competente desde a inspeção na produção, no registro até a fiscalização no comércio;

considerando ainda a necessidade de internalizar a Resolução Mercosul/GMC/Res. nº 72/98, que aprovou regulamento técnico contendo requisitos essenciais de segurança e eficácia de produtos médicos,

adota a seguinte Resolução de Diretoria Colegiada e eu Diretor-Presidente, determino a sua publicação.

Art. 1º Os produtos para saúde devem atender aos requisitos essenciais de segurança e eficácia aplicáveis a estes produtos, referidos no Regulamento Técnico anexo a esta Resolução.

Parágrafo único. Os produtos para saúde de que trata esta Resolução, são os produtos definidos como "correlatos" pela Lei nº 6.360/76 e o Decreto nº 79.094/77, excetuando-se os produtos para diagnóstico de uso invitro.

Art. 2º A verificação da conformidade dos produtos para saúde aos requisitos essenciais será realizada pela autoridade de vigilância sanitária por ocasião da inspeção das Boas Práticas de Fabricação, do registro dos produtos na ANVISA ou da fiscalização sanitária dos produtos.

Art. 3º O não cumprimento do disposto nesta Resolução implica na aplicação das penalidades previstas na legislação sanitária.

Art. 4º Esta Resolução entra em vigor na data de sua publicação.

GONZALO VECINA NETO

MERCOSUR

Brazilian Regulation for the Essential Principles of Safety and Performance

RDC 56/2001

Harmonized Regulation in Mercosur

Same requirements applied among the Mercosur member states

Argentina, Brazil, Paraguay and Uruguay
Total population - 268,5 M

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Essential Principles of Safety and Performance

IMDRF

MERCOSUR

ANVISA

Considering the need to update the regulations, Brazil proposed the adoption of the IMDRF technical document to the other member states of Mercosur

Final text approved by the Mercosur Sub-Commission of Medical Devices in May 2023, after internal Public Consultations

Internalization in progress

Expected to be published by Anvisa until November 2023

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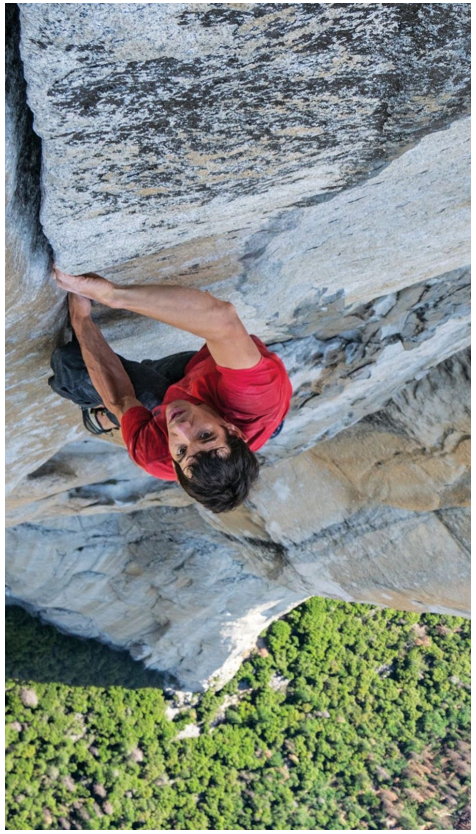
Essential Principles of Safety and Performance

Why update these essential principles?

1) Patient Safety
2) Rapid Technological Advancements
3) Equitable Access
4) Market Confidence
5) Global Harmonization
6) Data Privacy and Security
7) Adapting to Novel Risks
8) Clinical Efficacy
9) Innovation and Industry Growth
10) Ethical and Social Considerations



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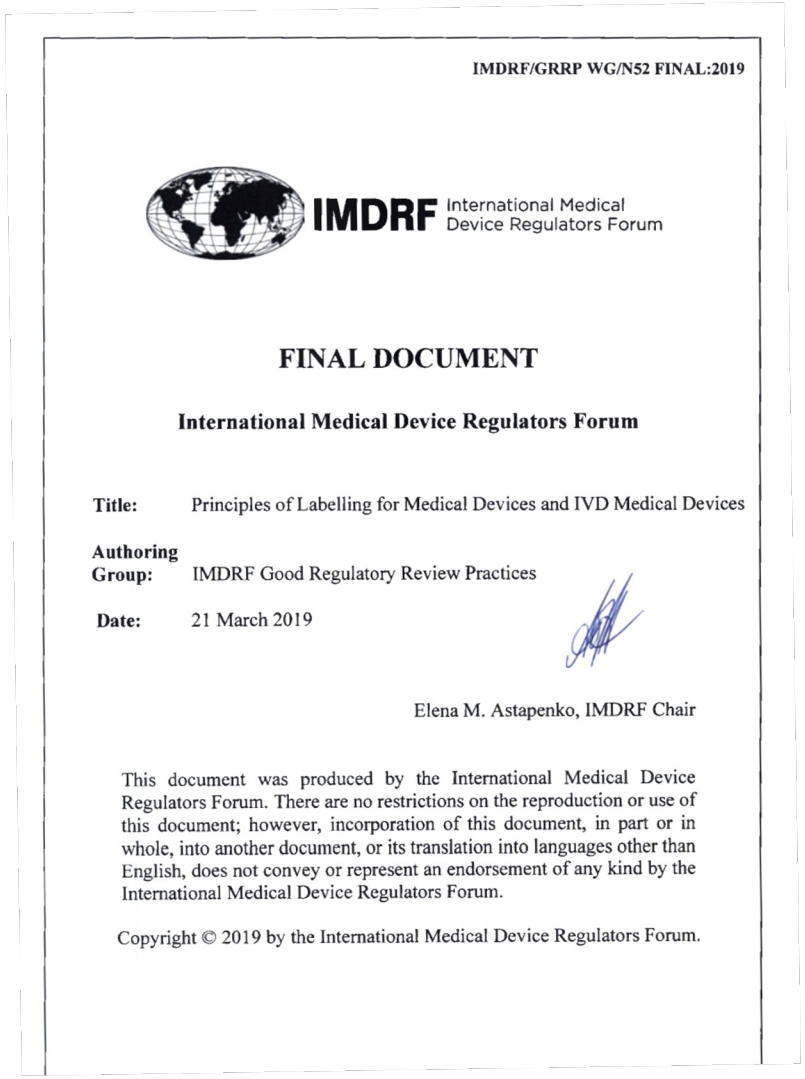
Essential Principles of Safety and Performance



IMDRF/GRRP WG/N52 FINAL:2019

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

International Medical Device Regulators Forum

Title: Principles of Labelling for Medical Devices and IVD Medical Devices

Authoring Group: IMDRF Good Regulatory Review Practices

Date: 21 March 2019

Elena M. Astapenko, IMDRF Chair

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Another important IMDRF document is directly linked to Safety and Performance Principles

IMDRF/GRRP WG/N52 FINAL:2019 Principles of Labelling for Medical Devices and IVD Medical Devices

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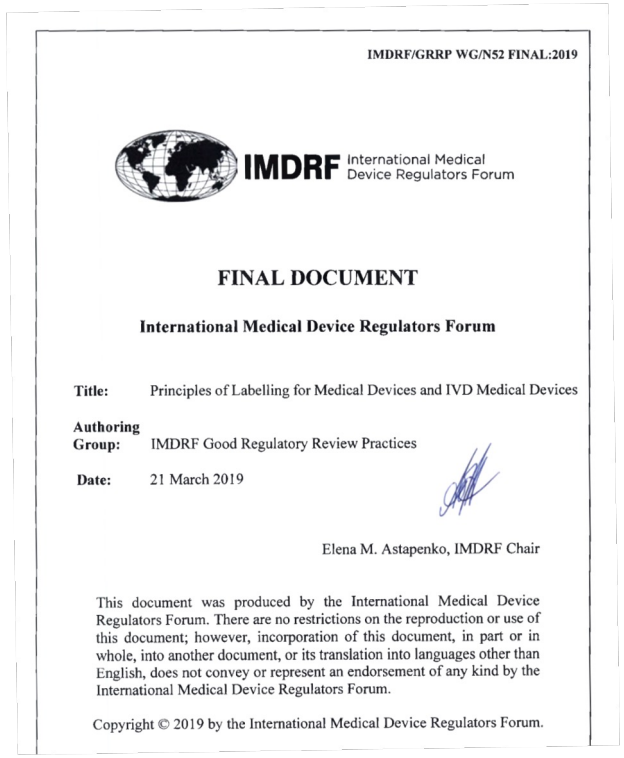
Essential Principles of Safety and Performance

Fundamental design and manufacturing requirements that provide assurance that a medical device or IVD is safe and performs as intended by the manufacturer



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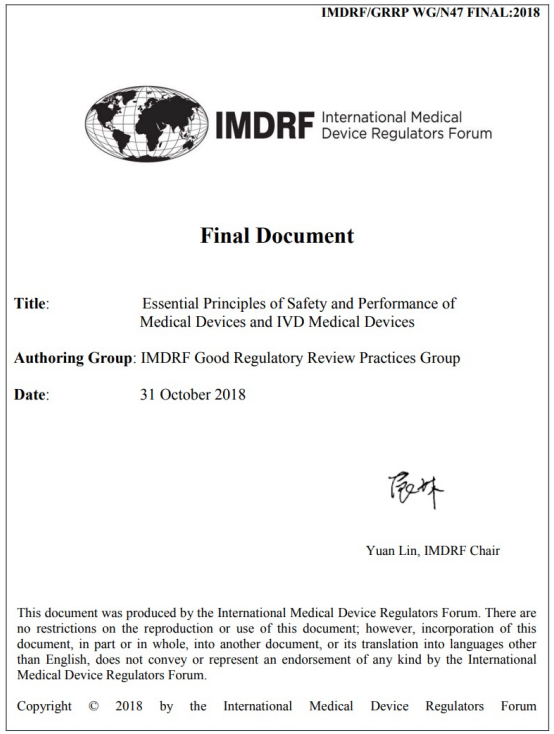

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Essential Principles of Safety and Performance

Safety and Performance

General and specific risk considerations specific to medical devices, IVDs, or both
Includes list of relevant standards/guidance documents

Examples:

- Material characterization
- Clinical evaluation
- Conditions of use
- Diagnostic functions
- Software aspects
- General labeling principles

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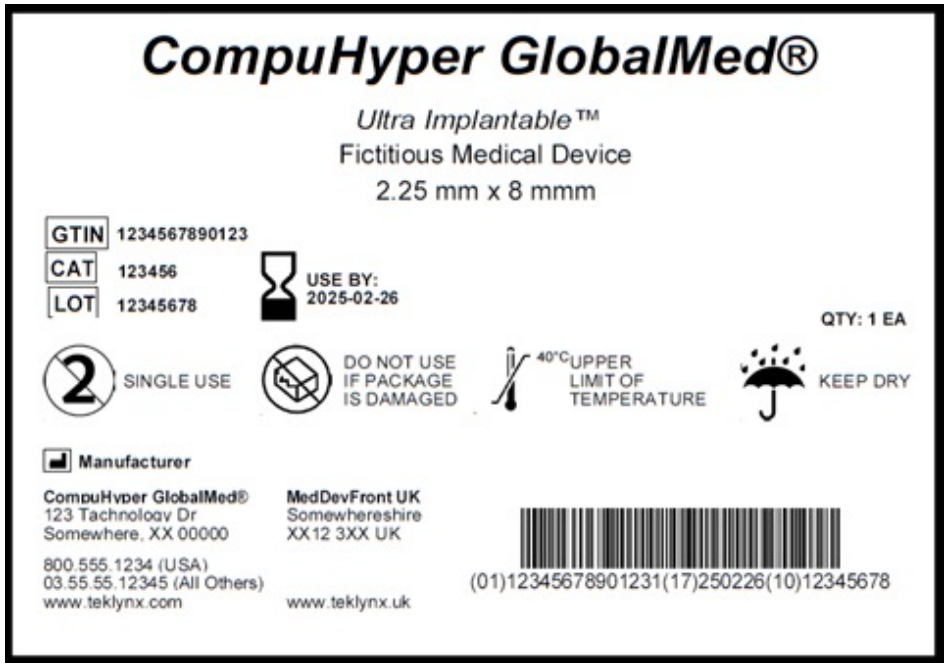
Essential Principles of Safety and Performance

Labeling

Labeling elements and information specific to medical devices, IVDs, or both

Examples:

- Label
- Instructions for use
- Software as a medical device
- Lay users
- Information intended for the patient



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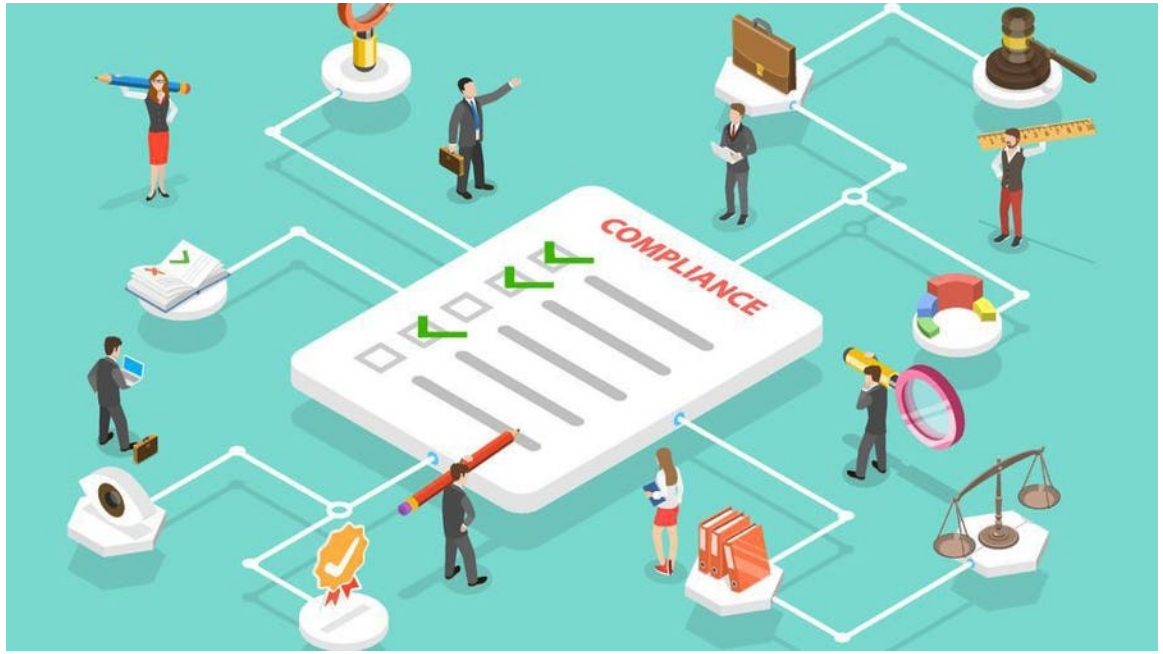
Essential Principles of Safety and Performance

The adoption of these common principles worldwide offers benefits to:

- Manufacturers
- Users
- Patients
- Regulatory authorities

Reducing regulatory compliance costs and enabling faster access to new medical technologies



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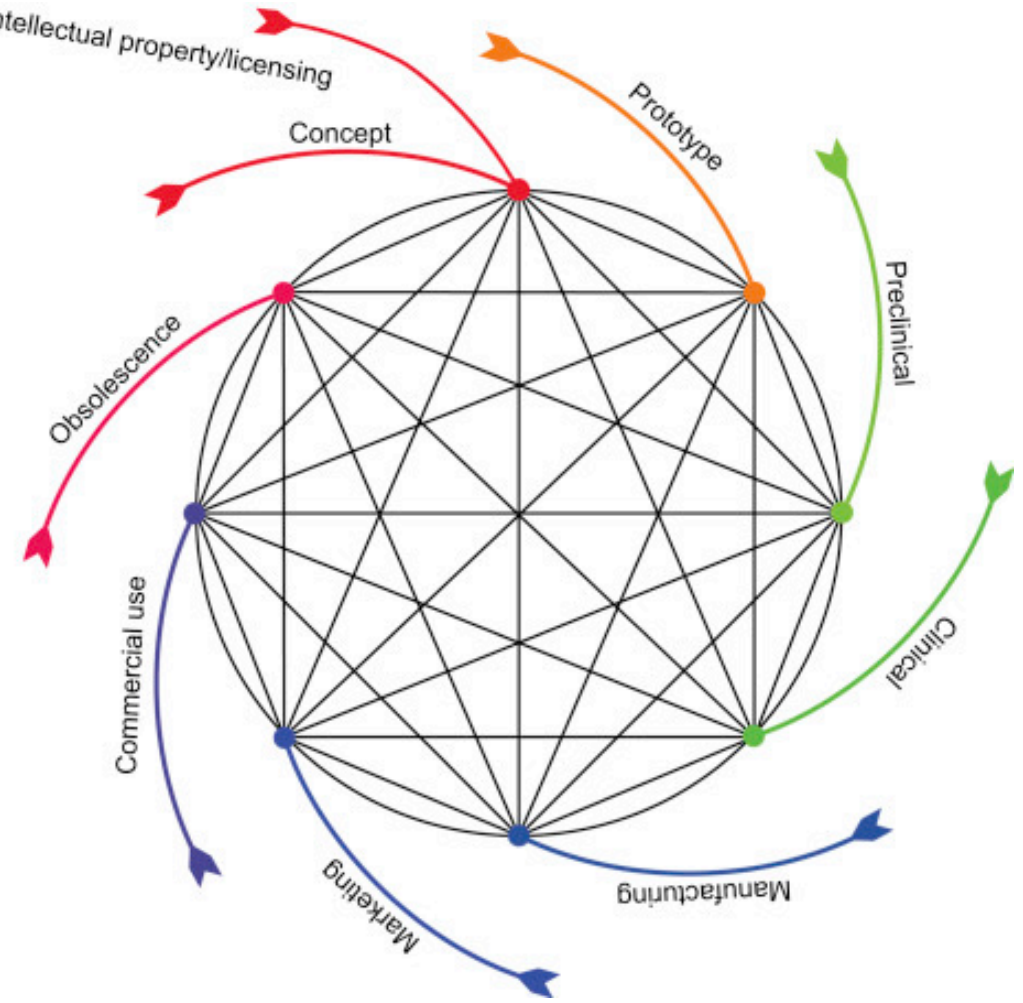
Essential Principles of Safety and Performance

Emphasizes a balance between safeguarding public health and not burdening the industry unnecessarily

Compliance to Essential Principles throughout product life-cycle

Design
Production
Postproduction



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Essential Principles of Safety and Performance

"Should" *indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited.*

"May" *is used to indicate that a course of action is permissible within the limits of the standard.*

"Can" *is used as a statement of possibility and capability.*

"Must" *is used only to describe "unavoidable" situations, including those mandated by government regulation.*

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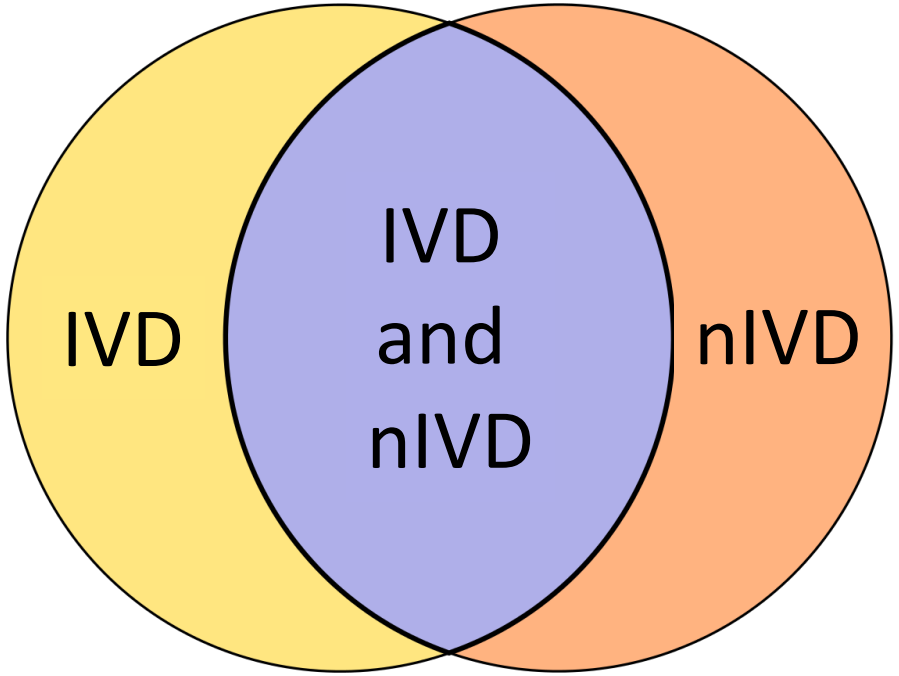
Essential Principles of Safety and Performance

A manufacturer of a medical device or IVD medical device ***is expected to design and manufacture*** *a product that is* ***safe and performs as intended*** *throughout its life cycle.*

Essential Principles Applicable to all Medical Devices and IVD Medical Devices

Essential Principles Applicable to Medical Devices other than IVD Medical Devices

Essential Principles Applicable to IVD Medical Devices



EP's Applicable to all Medical Devices and IVD Medical Devices

General

- Performance and Suitability
- Risk Management System
- Risk Management Steps
- Risk Control Measures
- Informing Users
- Risk Reduction for Users
- Performance Maintenance
- Transport and Storage
- Stability
- Balancing Risks and Benefits

- Develop a risk management plan for each device
- Identify and analyze known and foreseeable hazards associated with each device
- Evaluate the risks associated with intended use and foreseeable misuse
- Control or eliminate risks based on specific requirements
- Evaluate the impact of production and post-production information on overall risk
- Adjust control measures if necessary

EP’s Applicable to all Medical Devices and IVD Medical Devices

Clinical Evaluation

- This evaluation involves analyzing clinical data to confirm a positive balance between benefits and risks for the device
- This data can include reports from clinical investigations or performance evaluations, published scientific literature, and clinical experiences

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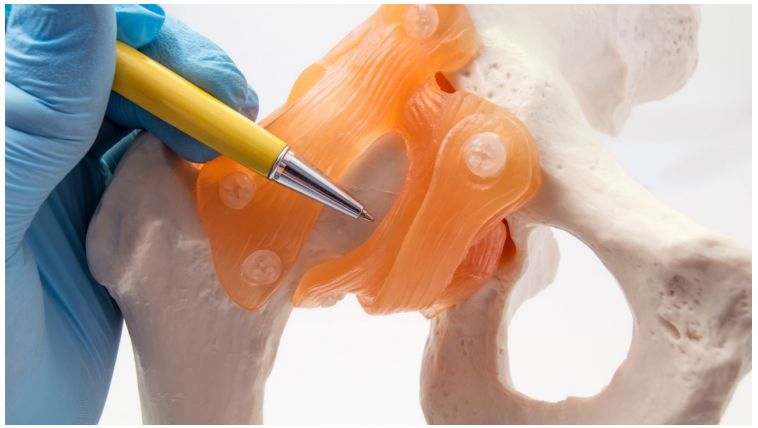
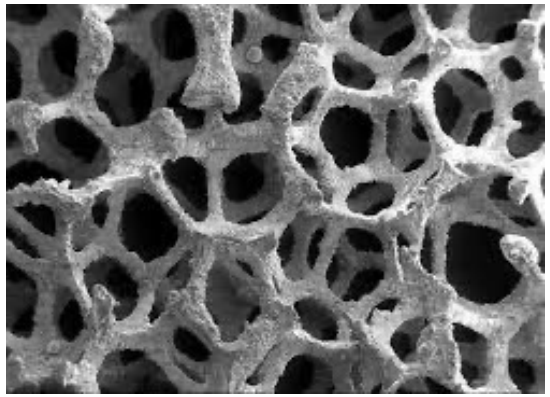
EP’s Applicable to all Medical Devices and IVD Medical Devices

Chemical, Physical, and Biological Properties

- Material Selection
- Process Impact
- Research Validation
- Mechanical Properties
- Surface Properties
- Chemical and Physical Specifications
- Contaminants and Residues
- Substance Egress
- Unintentional Substance Ingress
- Infection Risk





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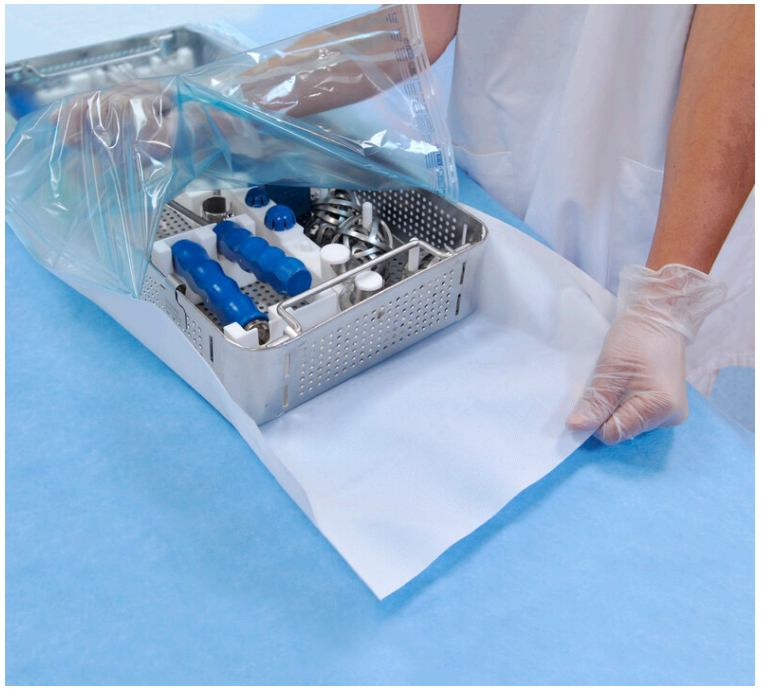
EP’s Applicable to all Medical Devices and IVD Medical Devices

Sterilization and Microbial Contamination

- Facilitate safe cleaning, disinfection, sterilization, and re-sterilization by the user
- Maintain microbial state during transportation and storage
- Validated methods for products labeled as sterile
- Packaging should minimize contamination when devices are provided non-sterile



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EP’s Applicable to all Medical Devices and IVD Medical Devices

Considerations of Environment and Conditions of Use

- Devices intended for use alongside other medical devices
  - The entire combination, including connection systems, must ensure safety and not compromise the specified performance

- Consider the intended environment and usage conditions to minimize various risks
  - Risks to users or others caused by physical features, user interface design, and foreseeable external influences like magnetic fields, humidity, temperature, and pressure

- Software interactions, maintenance and calibration mechanisms, unauthorized access risks, ergonomic usability, and safe disposal/recycling

EP’s Applicable to all Medical Devices and IVD Medical Devices

Devices that Incorporate Software or are Software as a Medical Device

- Ensure accuracy, reliability, safety, and performance
- In case of a single fault, measures should be taken to eliminate or reduce resulting risks
- Software should be developed, manufactured, and maintained using up-to-date practices, considering development cycles, risk management, verification, and validation
- When software is intended for use with mobile platforms, the platform's characteristics and usage environment should be considered
- Cybersecurity measures are also essential

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EP’s Applicable to all Medical Devices and IVD Medical Devices

Protection against the Risks posed by Devices intended for use by Lay Users

- Consider the capabilities and limitations of lay users
- IFU should be easy to comprehend
- Additional training might be required when risks remain
- Result interpretation
- Verification of the correct function of the device
- Alert to the user when the device fails to operate

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EP’s Applicable to all Medical Devices and IVD Medical Devices

Labeling

- Refer to IMDRF/GRRP WG/N52
- Information needed to distinctively identify the medical device or IVD medical device and its manufacturer
- Accompanied by, or direct the user to any safety and performance information relevant to the user, or any other person, as appropriate
- Information may appear on the device itself, on the packaging or in the instructions for use, or be readily accessible through electronic means, and should be easily understood by the intended user

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EP’s Applicable to all Medical Devices and IVD Medical Devices

Other important topics discussed in this section

- Protection against Electrical, Mechanical, and Thermal Risks
- Active Medical Devices and Devices Connected to Them
- Devices with a Diagnostic or Measuring Function
- Protection against Radiation
- Devices Incorporating Materials of Biological Origin

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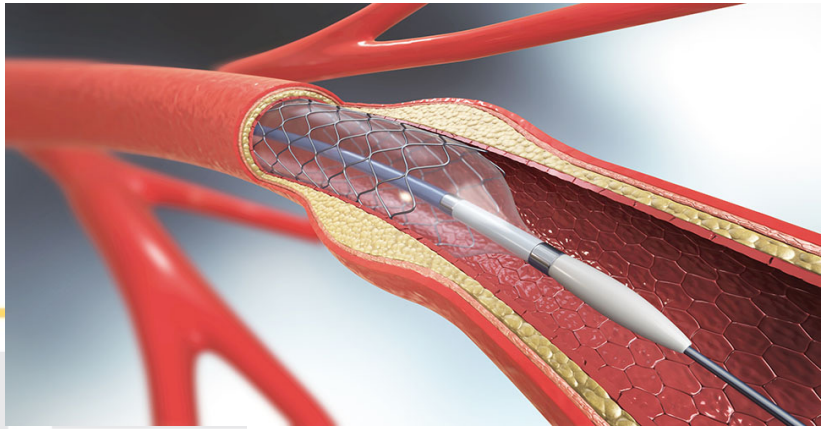
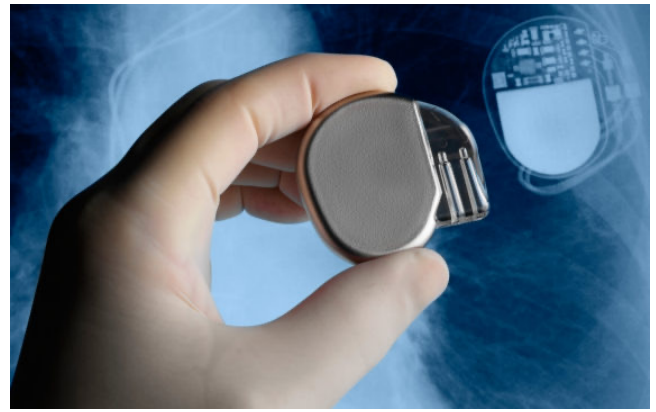
EP’s Applicable to Medical Devices other than IVD MD

Additional EP’s to the previously listed

- Chemical, Physical and Biological Properties
- Protection against Radiation
- Particular Requirements for Implantable Medical Devices
- Protection against the Risks Posed to the Patient or User by Medical Devices Supplying Energy or Substances
- Medical Devices Incorporating a Substance Considered to be a Medicinal Product/Drug





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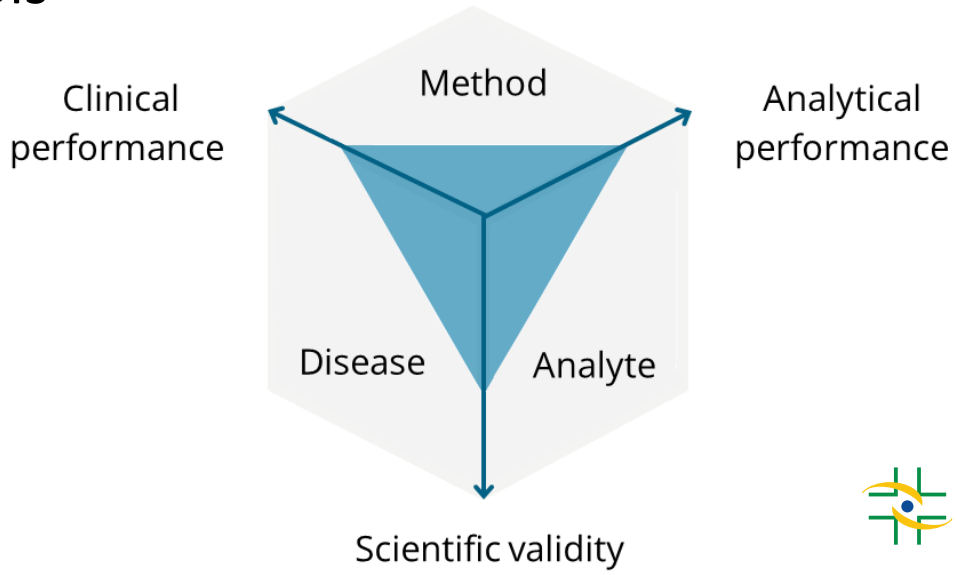
EP’s Applicable to IVD Medical Devices

Additional EP’s to the previously listed

- Chemical, Physical and Biological Properties
- Performance Characteristics
  - Analytical performance
  - Clinical performance
  - Validated control procedures
- Traceability of Calibrators and Controls
- Standardized Units
- Performance Evaluation



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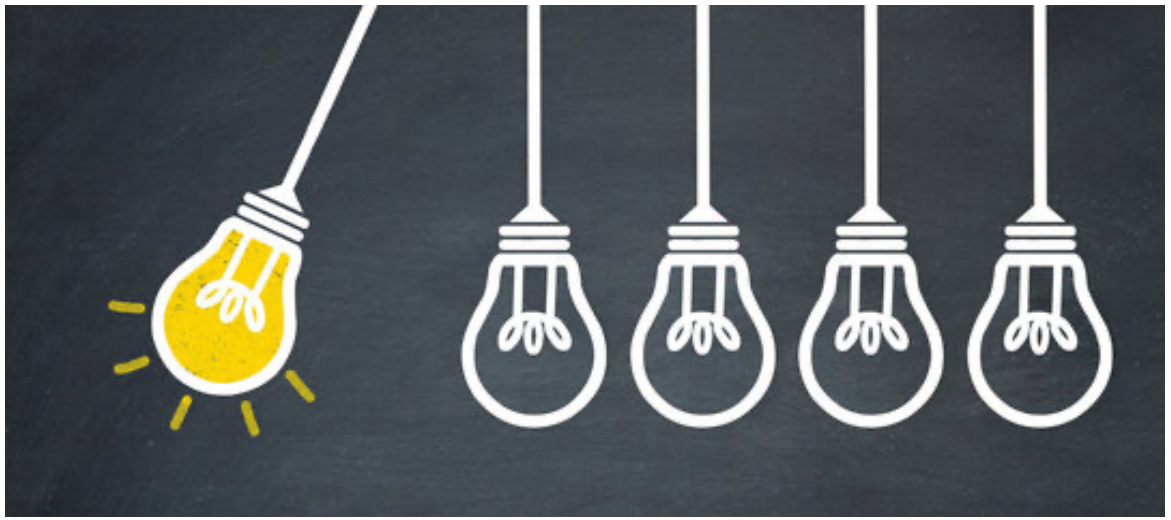
Conclusion

Essential Principles of Safety and Performance for MD and IVD MD

- Trust and reliability in the technologies
- Innovation with responsibility
- Maximize patient well-being while minimizing risks
- High standards
- Contribute to the advancement of medical science



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THANK YOU!
OBRIGADO!

MEDICAL DEVICES OFFICE

Brazilian Health Regulatory Agency
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