National Directorate of Medicines (DNM)

Measures to align El Salvador's medical device regulatory framework with international references

March 14th, 2024

Mario Ernesto Vega Valenzuela

Head of the Medical Device Registration Unit

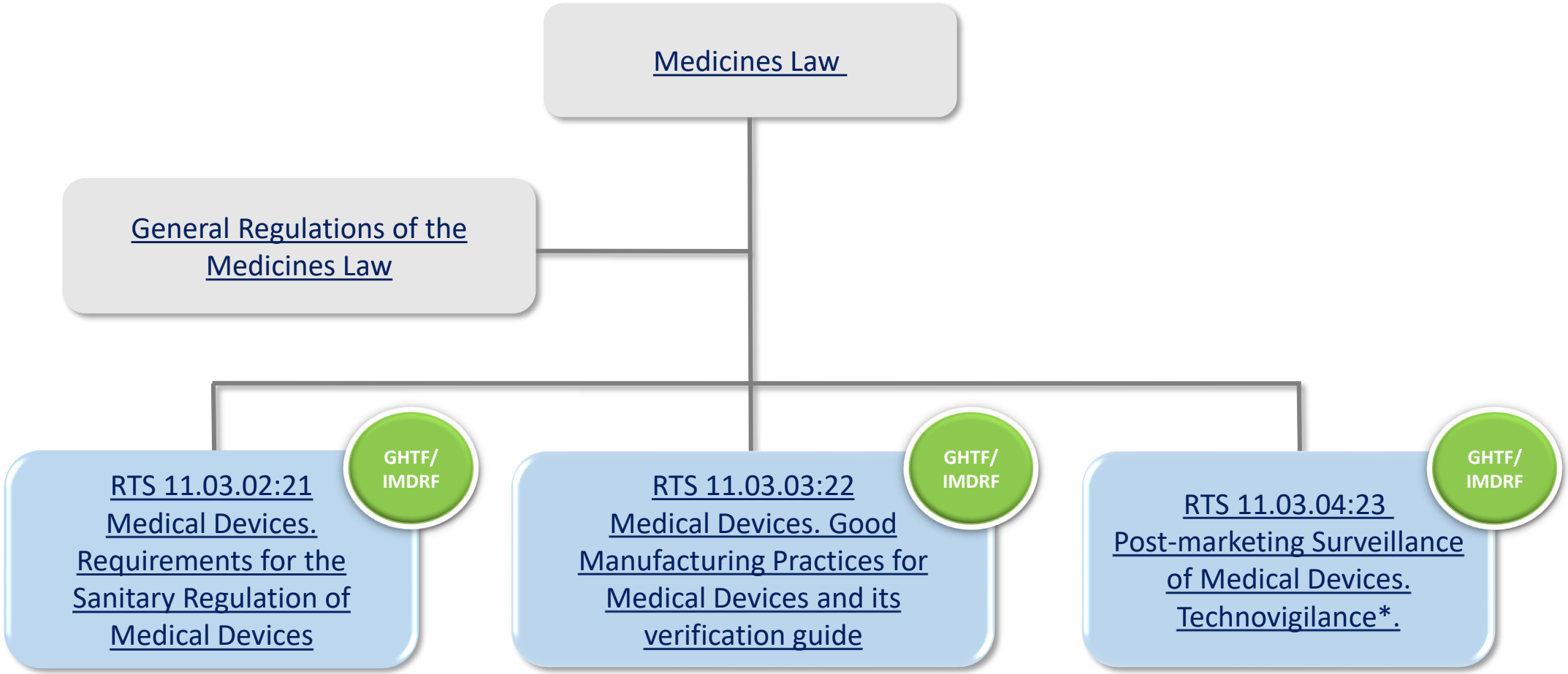
About DNM


Post-
Marketing
Product
development
Risk
evaluation and
pre-clinical
Clinical
investigation
and
evaluation
Production
and quality
control
Marketing
and sales
Distribution
and use
El Salvador
San Salvador
DNM
2012


Hygiene Products
Chemicals
Medical Devices
Pharmaceuticals
Raw materials
Cosmetics

Salvadoran medical devices regulatory framework

Regulatory framework for medical devices



* Currently awaiting publication in the official gazette.

How are Salvadoran Technical Regulations elaborated?

Regular Procedure for the Elaboration of Salvadoran Technical Regulations

Since September 2011, with the entry into force of the Law of Creation of the Salvadoran Quality Council, published in Official Gazette No. 158, Volume 392, activities related to Technical Regulation were entrusted to the Salvadoran Technical Regulation Body (OSARTEC, by its acronym in Spanish) which is legally empowered to coordinate the adoption, adaptation, updating, and dissemination of technical regulations within its jurisdiction issued by different government institutions. Additionally, it is empowered to issue regulations necessary for the proper functioning of the Systems.

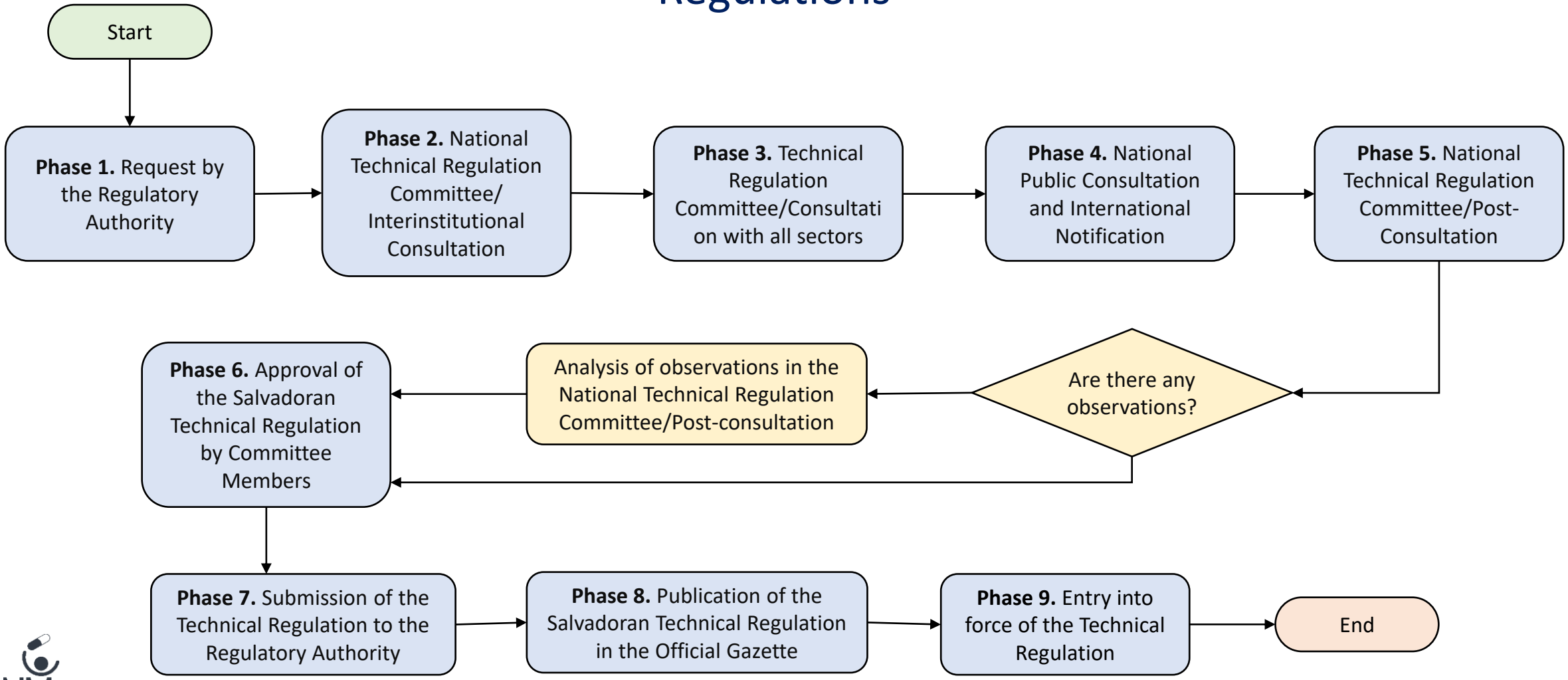
For more details, you can consult the CNC website.

Good Technical Regulation Practices Guidance

- Transparency
- Non-discrimination
- National treatment

Following the WTO, OECD and APEC recommendations to regulatory strengthening on a global perspective.

OSARTEC Regular Procedure for the Elaboration of a Salvadoran Technical Regulations



For more details, you can consult the Regulation for the elaboration of Salvadoran Technical Regulations

Key international references in the development of Salvadoran Technical Regulations for medical devices

International References in Salvadoran Technical Regulations

WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices

Annexes 10 and 11. WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-fifth report

GHTF and IMDRF documents

Salvadoran Technical Regulations

Future strategy for international references implementation

Superintendencia de Regulación Sanitaria/Superintendency of Sanitary Regulation

SRS
Authority to issue its own regulation

REPUBLICA DE EL SALVADOR EN LA AMERICA CENTRAL 1

DIARIO OFICIAL

DIRECTORA: Nilda Verónica Menéndez Gil

TOMO Nº 441 | SAN SALVADOR, LUNES 4 DE DICIEMBRE DE 2023 | NUMERO 227

La Dirección de la Imprenta Nacional hace del conocimiento que toda publicación en el Diario Oficial se procesa por transcripción directa y fiel del original, por consiguiente la institución no se hace responsable por transcripciones cuyos originales lleguen en forma ilegible y/o defectuosa y son de exclusiva responsabilidad de la persona o institución que los presentó. (Arts. 21, 22 y 23 Reglamento de la Imprenta Nacional).

SUMARIO

Pág.

ÓRGANO LEGISLATIVO

Decreto No. 891.- Ley de Superintendencia de Regulación Sanitaria. 4-27

Pág.

MINISTERIO DE ECONOMÍA

RAMO DE ECONOMÍA

National Technical Regulations aligned with IMDRF documents

GHTF and IMDRF documents implemented

RTS 11.03.02:21 establishes the technical provisions governing the health regulation of medical devices within the national territory, based on current legal frameworks and internationally harmonized principles for Good Regulatory Practices. It aligns with GHTF and IMDRF documents through the following elements:

REGLAMENTO TÉCNICO SALVADOREÑO

RTS 11.03.02:21

DISPOSITIVOS MÉDICOS. REQUISITOS PARA LA REGULACIÓN SANITARIA DE DISPOSITIVOS MÉDICOS.

Correspondencia: este Reglamento Técnico Salvadoreño no tiene correspondencia con normativa internacional.

ICS 11.140.01

RTS 11.03.02:21

Editado por el Organismo Salvadoreño de Reglamentación Técnica, ubicado en Boulevard San Bartolo y Calle Lempa, costado Norte del INSAFORP, Edificio CNC, Ilopango, San Salvador, El Salvador. Teléfono (503) 2590-5335 y (503) 2590-5338. Sitio web: www.osartec.gob.sv

Elements	GHTF / IMDRF documents
Definitions of manufacturer, distributor and Importer.	GHTF/SG1/N055:2009 Definitions of the Terms Manufacturer, Authorized Representative, Distributor and Importer.
Definition of "Medical Devices".	GHTF/SG1/N071:2012 Definition of the Terms “Medical Device” and “In Vitro Diagnostic (IVD) Medical Device”.
General section about Essential Principles of Safety and Performance of Medical Devices.	IMDRF/GRRP WG/N47 FINAL:2018 Essential Principles of Safety and Performance of Medical Devices
General recommendations for labelling.	IMDRF/GRRP WG/N52 Principles of Labelling for Medical Devices and IVD Medical Devices
Registration of manufacturers and their medical devices by the Regulatory Authority.	GHTF/SG1/N78:2012 Principles of Conformity Assessment for Medical Devices
Definition of " Software as a Medical Device	IMDRF/SaMD WG/N10FINAL:2013 Software as a Medical Device (SaMD): Key Definitions
Principles of Medical Devices Classification.	GHTF/SG1/N77:2012 Principles of Medical Devices Classification
Information for registration and role of the registering party.	GHTF/SG1/N065:2010 Registration of Manufacturers and other Parties and Listing of Medical Devices
Technical requirements	GHTF/SG1/N044:2008 Role of Standards in the Assessment of Medical Devices

GHTF and IMDRF documents implemented

RTS 11.03.03:22 establishes the principles and guidelines of Good Manufacturing Practices, which regulate all procedures involved in the manufacturing of medical devices, with the aim of ensuring their effectiveness, safety, and quality. It aligns with GHTF and IMDRF documents through the following elements:

REGLAMENTO TÉCNICO SALVADOREÑO

RTS 11.03.03:22

DISPOSITIVOS MÉDICOS. BUENAS PRÁCTICAS DE MANUFACTURA DE DISPOSITIVOS MÉDICOS Y SU GUÍA DE VERIFICACIÓN.

Correspondencia: este Reglamento Técnico Salvadoreño tiene correspondencia parcial con la norma ISO13485:2016 Productos sanitarios. Sistemas de gestión de la calidad. Requisitos con fines reglamentarios.

ICS 11.140.01

RTS 11.03.03:22

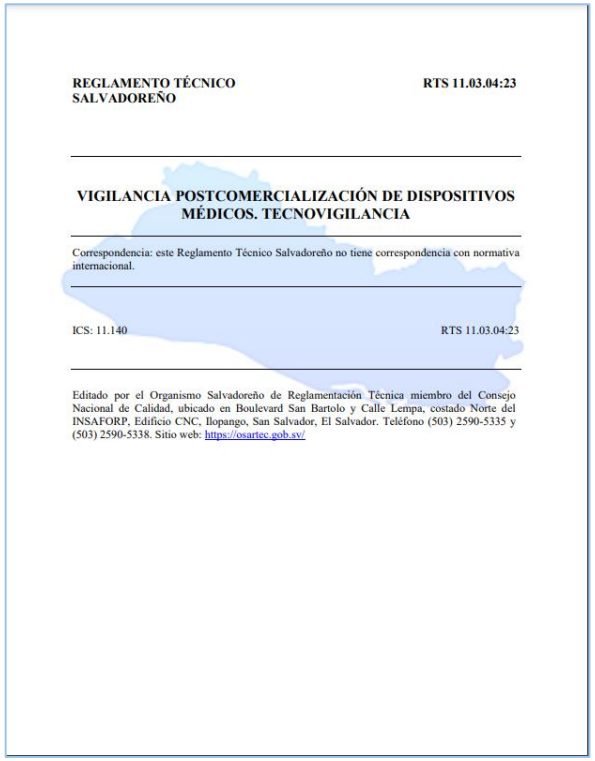
Editado por el Organismo Salvadoreño de Reglamentación Técnica, ubicado en Boulevard San Bartolo y Calle Lempa, costado Norte del INSAFORP, Edificio CNC, Ilopango, San Salvador, El Salvador. Teléfono (503) 2590-5335 y (503) 2590-5338. Sitio web: www.osartec.gob.sv

Derechos Reservados.

Elements	GHTF / IMDRF documents
Definition of "Medical Devices".	GHTF/SG1/N071:2012 Definition of the Terms “Medical Device” and “In Vitro Diagnostic (IVD) Medical Device”.
Declaration of conformity.	GHTF/SG1/N78:2012 Principles of Conformity Assessment for Medical Devices
Definition of " Software as a Medical Device”.	IMDRF/SaMD WG/N10FINAL:2013 Software as a Medical Device (SaMD): Key Definitions
Principles of Medical Devices Classification.	IMDRF/SaMD WG/N12FINAL:2014 "Software as a Medical Device": Possible Framework for Risk Categorization and Corresponding Considerations.
Guide for the evaluation of SaMD manufacturer’s.	IMDRF/SaMD WG/N41FINAL:2017 Software as a Medical Device (SaMD): Clinical Evaluation.

GHTF and IMDRF documents implemented

RTS 11.03.04:23 establishes the technical provisions for the development and implementation of nationwide medical device vigilance, in accordance with current legal frameworks and internationally harmonized principles in the field. It aligns with GHTF and IMDRF documents through the following elements:



REGLAMENTO TÉCNICO SALVADOREÑO

RTS 11.03.04:23

VIGILANCIA POSTCOMERCIALIZACIÓN DE DISPOSITIVOS MÉDICOS. TECNOVIGILANCIA

Correspondencia: este Reglamento Técnico Salvadoreño no tiene correspondencia con normativa internacional.

ICS: 11.140

RTS 11.03.04:23

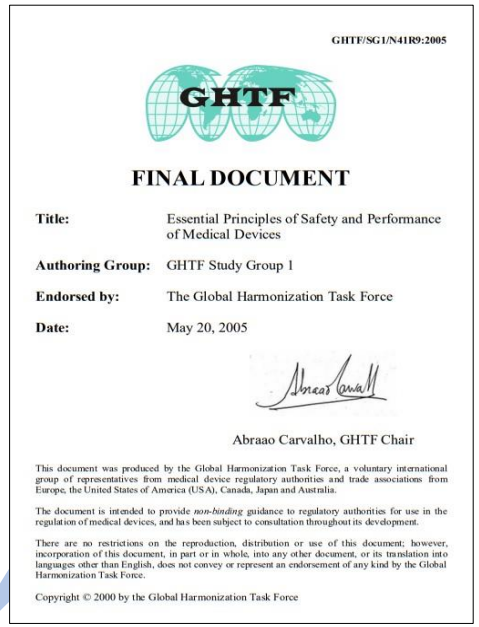
Editado por el Organismo Salvadoreño de Reglamentación Técnica miembro del Consejo Nacional de Calidad, ubicado en Boulevard San Bartolo y Calle Lempa, costado Norte del INSAFORP, Edificio CNC, Ilopango, San Salvador, El Salvador. Teléfono (503) 2590-5335 y (503) 2590-5338. Sitio web: https://osartec.gob.sv/

Elements	GHTF / IMDRF documents
Definitions of manufacturer, distributor and Importer.	GHTF/SG1/N055:2009 Definitions of the Terms Manufacturer, Authorized Representative, Distributor and Importer.
Definition of "Medical Devices".	GHTF/SG1/N071:2012 Definition of the Terms “Medical Device” and “In Vitro Diagnostic (IVD) Medical Device”.
Whom to report the adverse event and the content of it	GHTF/SG2/N54R8:2006 Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices
Definitions and Field Safety Corrective Action notification	GHTF/SG2/N57R8:2006 Medical Devices Post Market Surveillance: Content of Field Safety Notices
	GHTF-SG2- N008R4 Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices

Essential Principles of Safety and Performance of Medical Devices

Essential Principles of Safety and Performance of Medical Devices

Essential Principles of Safety and Performance of Medical Devices
Date: May 20th, 2005



GHTF/SG1/N41R9:2005

GHTF

FINAL DOCUMENT

Title: Essential Principles of Safety and Performance of Medical Devices

Authoring Group: GHTF Study Group 1

Endorsed by: The Global Harmonization Task Force

Date: May 20, 2005

Abraao Carvalho, GHTF Chair

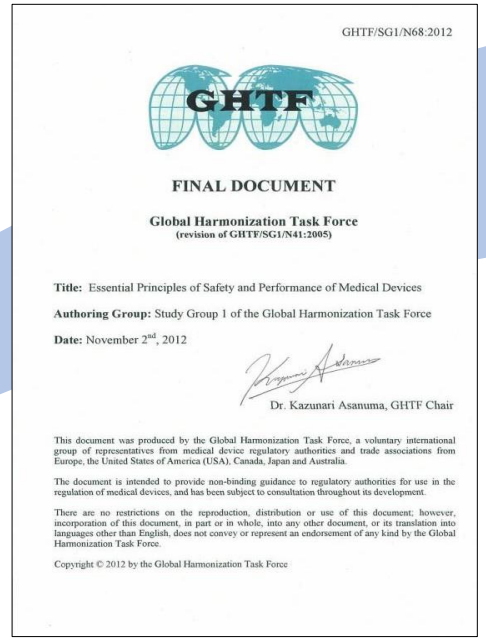
This document was produced by the Global Harmonization Task Force, a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia.

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.

There are no restrictions on the reproduction, distribution or use of this document; however, incorporation of this document, in part or in whole, into any other document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the Global Harmonization Task Force.

Copyright © 2000 by the Global Harmonization Task Force

Essential Principles of Safety and Performance of Medical Devices
Date: November 2nd, 2012



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

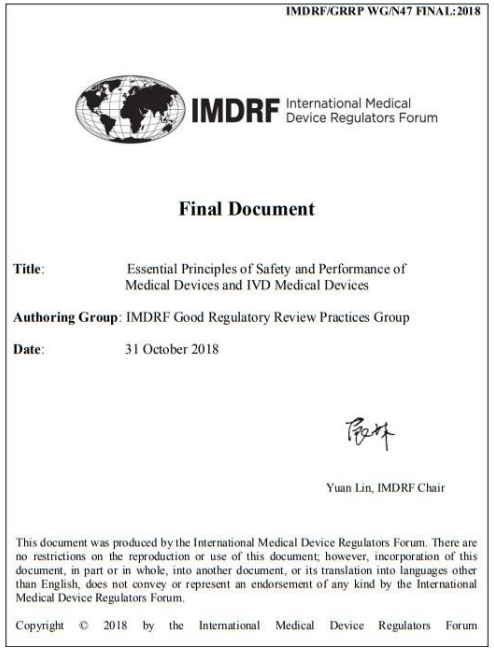
This document was produced by the Global Harmonization Task Force, a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia.

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.

There are no restrictions on the reproduction, distribution or use of this document; however, incorporation of this document, in part or in whole, into any other document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the Global Harmonization Task Force.

Copyright © 2012 by the Global Harmonization Task Force

Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices
Date: 31st October, 2018



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

This document was produced by the International Medical Device Regulators Forum. There are no restrictions on the reproduction or use of this document; however, incorporation of this document, in part or in whole, into another document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the International Medical Device Regulators Forum.

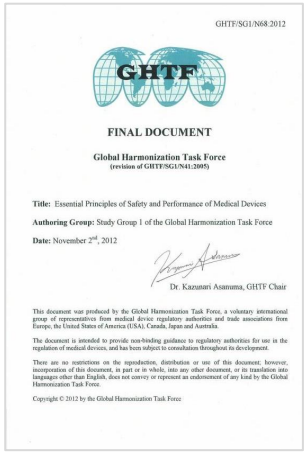
Copyright © 2018 by the International Medical Device Regulators Forum

Essential Principles of Safety and Performance of Medical Devices

Organización Mundial de la Salud

+

IMDRF


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.

There are no restrictions on the reproduction, distribution or use of this document; however, incorporation of this document, in part or in whole, into any other document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the Global Harmonization Task Force.

Copyright © 2012 by the Global Harmonization Task Force

=

DNM

Technical requirements the marketing authorization of medical devices in El Salvador

DNM

Essential Principles of Safety and Performance of Medical Devices

	PRINCIPLES	DNM REQUIREMENT
General essential principles	1. Medical devices should be designed and manufactured to perform as intended by the manufacturer, without compromising patient safety or the safety and health of users or other individuals.	Clinical evaluation studies / Validation report
	2. The solutions adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risks so that the residual risk associated with each hazard is judged acceptable.	Risk management report
	3. Medical devices should achieve the performance intended by the manufacturer and be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose.	Clinical evaluation studies / Valid ation report
	4. The characteristics and performances referred to in Clauses A1, A2 and A3 should not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device,	Technical document supporting the medical device's shelf life
	5. Medical devices should be designed, manufactured and packaged in such a way that their characteristics and performances during their intended use will not be adversely affected by transport and storage conditions.	Transport and storage conditions
	6. All known and foreseeable risks, and any undesirable effects, should be minimised and be acceptable when weighed against the benefits of the intended performance of medical devices during normal conditions of use.	Clinical evaluation studies / Valid ation report

Essential Principles of Safety and Performance of Medical Devices

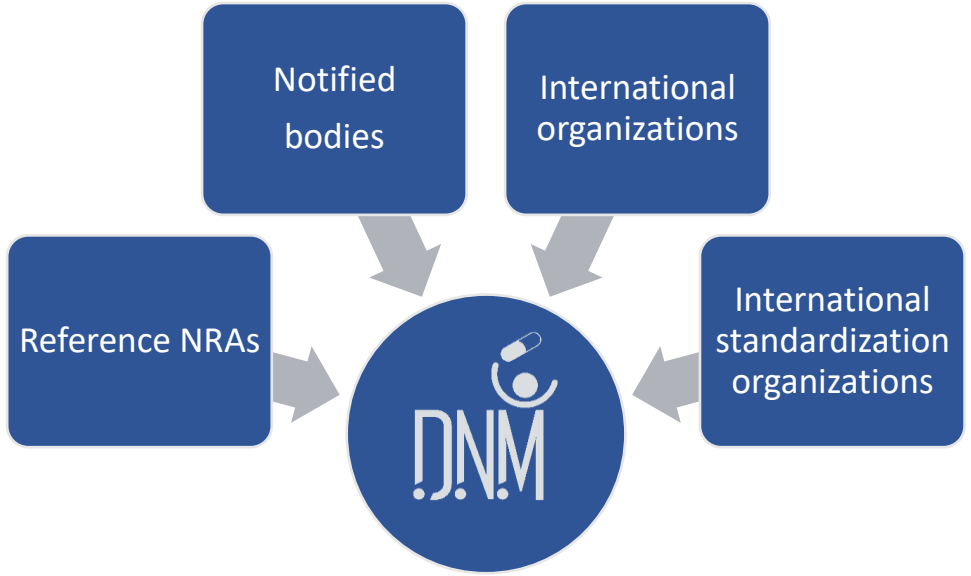
	PRINCIPLES	DNM REQUIREMENT
Design and manufacturing principles	1. Chemical, physical and biological properties	Clinical evaluation studies / Validation report and Safety data sheet
	2. Infection and microbial contamination	Sterilization certificate
	3. Medical devices incorporating a substance considered to be a medicinal product/drug	GMP certificate of the drug manufacturer
	4. Medical devices incorporating materials of biological origin	Clinical evaluation studies
	5. Environmental properties	Risk Management Report and Safety Data Sheet
	6. Devices with a diagnostic or measuring function	Certificate of Analysis or Test Report
	7. Protection against radiation	Certificate of Analysis or Test Report
	8. Medical devices that incorporate software and standalone medical device software	Software specific requirements
	9. Active medical devices and devices connected to them	Certificate of Analysis or Test Report
	10. Protection against mechanical risks	Certificate of Analysis or Test Report
	11. Protection against the risks posed to the patient or user by supplied energy or substances	Risk Management Report and Safety Data Sheet
	12. Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons	Risk Management Report and Instructions for Use
	13. Label and Instructions for Use	Labeling and IFU/Manual
	14. Evaluación Clínica	Clinical evaluation studies / Validation report

Reliance Application for Medical Devices in El Salvador

Reliance Application for Medical Devices in El Salvador

The DNM applies unilateral reliance for medical devices, mainly in the following cases:

- Public health emergencies
- Marketing authorization
- Post-market surveillance

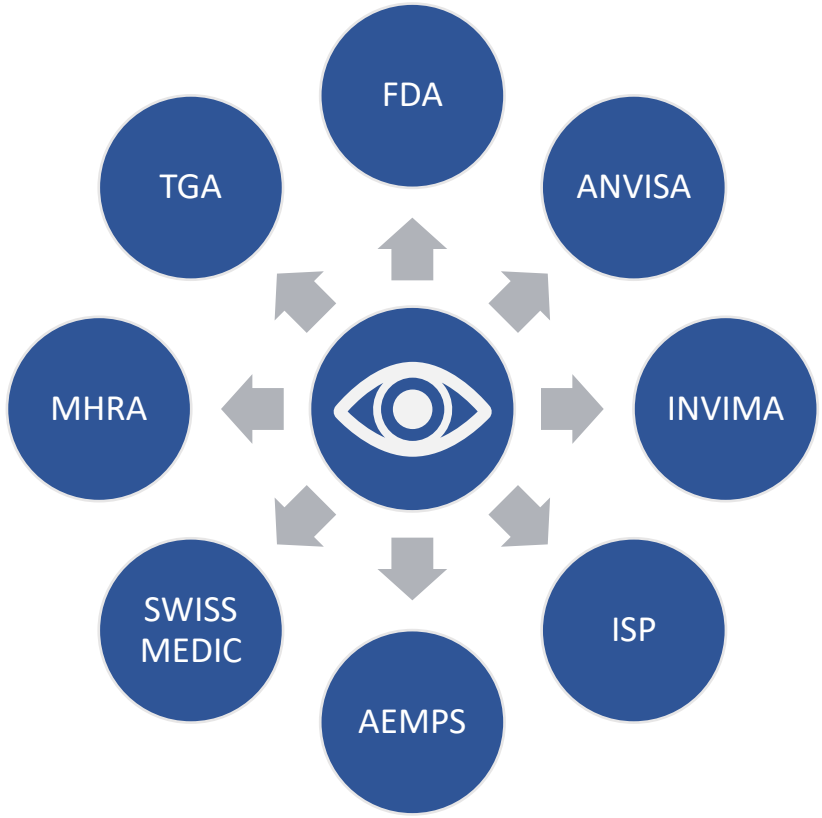


Recognition of MDSAP, ISO and EU certificates

The DNM recognizes certificates issued under the Medical Device Single Audit Program (MDSAP). A global initiative to audit and monitor the manufacturing of medical devices. This program allows Auditing Organizations recognized by it to conduct a single regulatory audit of medical device manufacturers that meets the requirements of all regulatory authorities participating in the program.

Additionally, ISO 13485 certificates and certificates of conformity with European Regulations 745/2017 and 746/2017 are recognized as equivalent to GMP certificates.

Reliance application in medical device surveillance function



Sanitary registration? → Import control? → CNTV investigation process

This monitoring involves the initiation of a case, in which the actions taken by the monitored agency are taken into account; however, CNTV conducts its own investigation process.

Thank you/Questions

Contact information:

Cooperation and Strategic Alliances Unit

Email sulay.mejia@medicamentos.gob.sv
cooperacion@medicamentos.gob.sv