



RECOGNITION OF INTERNATIONAL STANDARDS APPLIED TO MEDICAL DEVICES IN LATIN AMERICA

Carlos Eduardo Gouvêa
IMDRF
Ottawa, September 2017

ALADDIV



**The Latin American Alliance for the Development
of In Vitro Diagnostics**



Rosanna Peeling , Carlos Gouvea , Adele Benzaken, Graciela Russomando
Alain Mérieux, Patricia Velez Moller e Segundo Leon

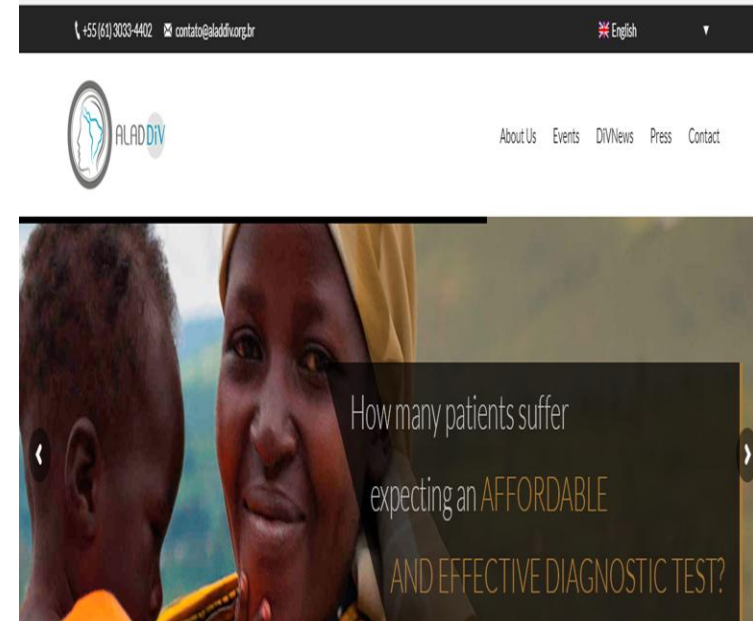
ALADDIV



The Latin American Alliance for the Development of In Vitro Diagnostics

Non-profit organization, created in 2012, acting in the whole Latin America region, through a network of collaborating members (academy, industries, governments).

Defense of the harmonization or normative convergence that allows a greater predictability and the cooperation between American countries, especially in Public Health Programs.



www.aladdiv.org.br

AMID	MÉXICO
ASEDIM	ECUADOR
COMSALUD	PERÚ
ABIIS ABIMED CBDL ABRAIDI ABIMO	BRASIL
SDCM	CHILE
CADIEM	ARGENTINA
AVEDEM	VENEZUELA
ANDI	COLOMBIA





INTERNATIONAL WORKSHOPS

“Accessible and Quality Assured *in Vitro* Diagnostic Tests for Public Health Programs”

- Brazil (Brasília), April 2012 (PAHO)
- Brazil (Brasília), November 2012 (ANVISA)
- Brazil (Curitiba), October / November 2013 (TECPAR)
- Brazil (Brasília), November 2014 (ParlaMundi/LBV)
- Peru (Lima), May 2015 (Universidad C. Heredia)
- Brazil (Florianópolis), September 2016 (IMDRF)
- Canada (Ottawa), September 2017 (IMDRF/PAHO)



I Workshop Internacional

17 e 18 de abril de 2012 - Brasília - DF

Padrões de qualidade e ausência de investimentos na área preocupam setor de diagnósticos na América Latina.

[Veja mais ▶](#)



II Workshop Internacional

19 e 20 de novembro de 2012 - Brasília - DF

Participantes de workshop internacional sobre Testes de Diagnóstico in Vitro (IVD) decidem criar entidade para atuar na América Latina.

[Veja mais ▶](#)



III Workshop Internacional

30 e 31 de outubro e 01 de novembro de 2013 - Curitiba - PR

Testes de Diagnóstico com Qualidade Assegurada e Acessível para Programas de Saúde Pública.

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IV Workshop Internacional

03 a 05 de novembro de 2014 – Brasília – DF
Testes de Diagnóstico com Qualidade Assegurada e
Acessíveis para Programas de Saúde Pública,

[Veja mais ▶](#)



V Workshop Internacional

13 e 15 de maio de 2015 – Lima – Peru
Testes de Diagnóstico com Qualidade Assegurada e
Acessíveis para Programas de Saúde Pública,

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VI Workshop Internacional

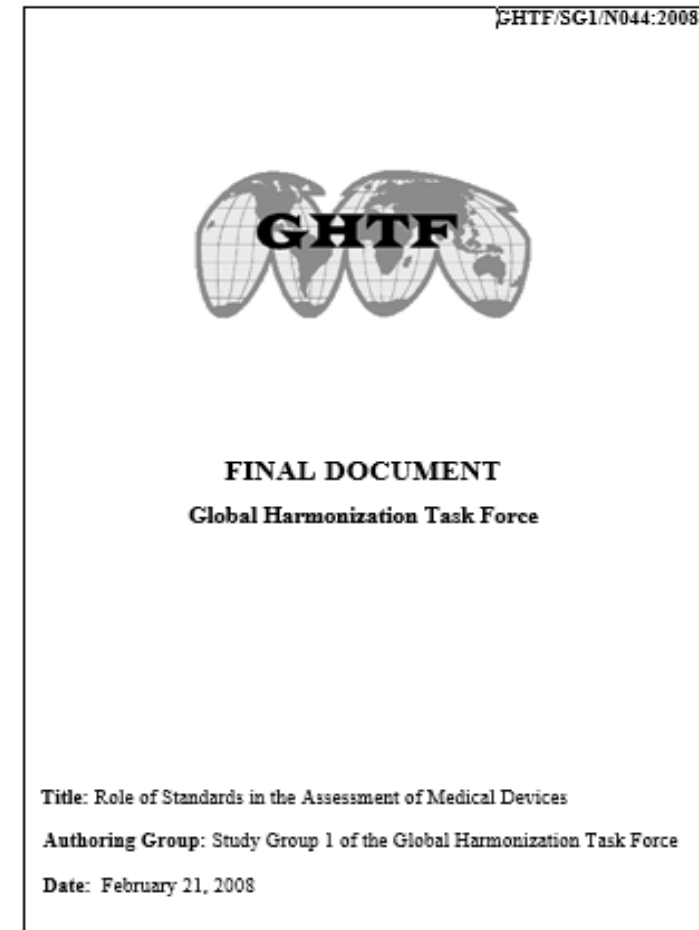
15 de setembro de 2016 – Florianópolis – SC
Testes rápidos e convergência regulatória foram
destaques em workshop internacional em Santa
Catarina...

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INTERNATIONAL STANDARDS APPLIED TO MEDICAL DEVICES IN LATIN AMERICA



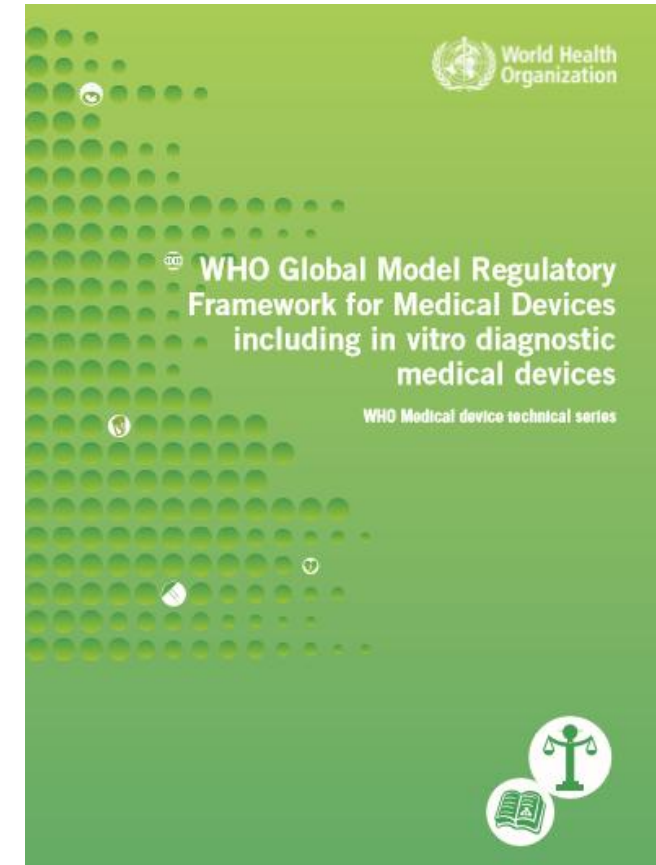
International consensus standards are a tool for harmonizing regulatory processes to assure the safety, quality and performance of medical devices.



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Conformity with voluntary standards is a means by which the manufacturer may demonstrate that a medical device conforms to one or more of the Essential Principles of safety and performance, consistently throughout its life cycle .



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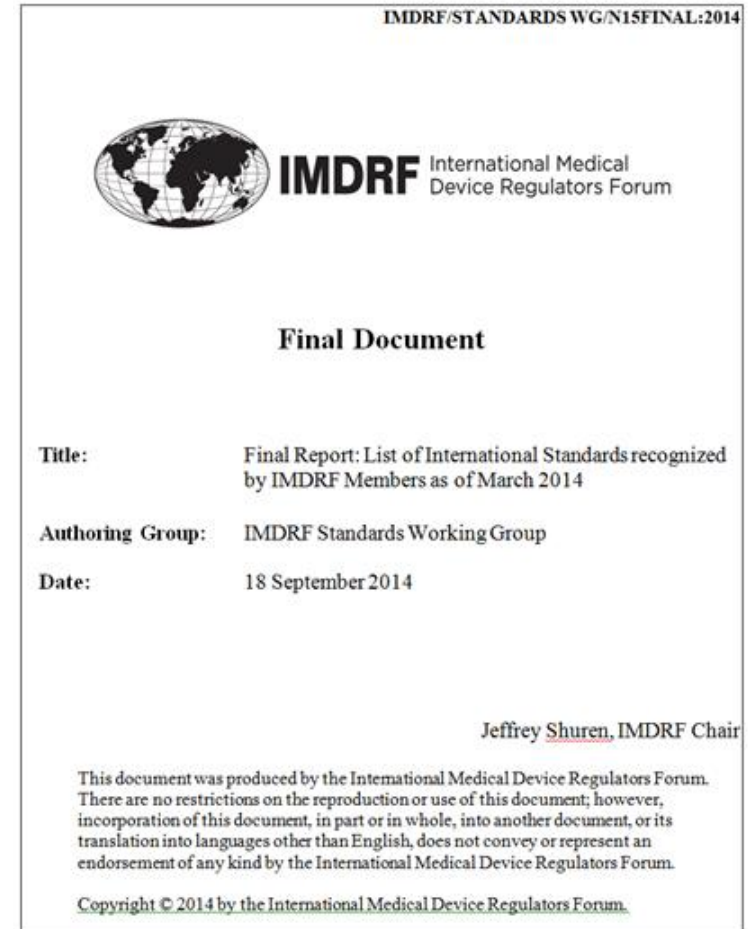


IMDRF/Standards/N15FINAL:2014

Final Report:

“List of international standards recognized by IMDRF management committee members”

Current as of: March 2014



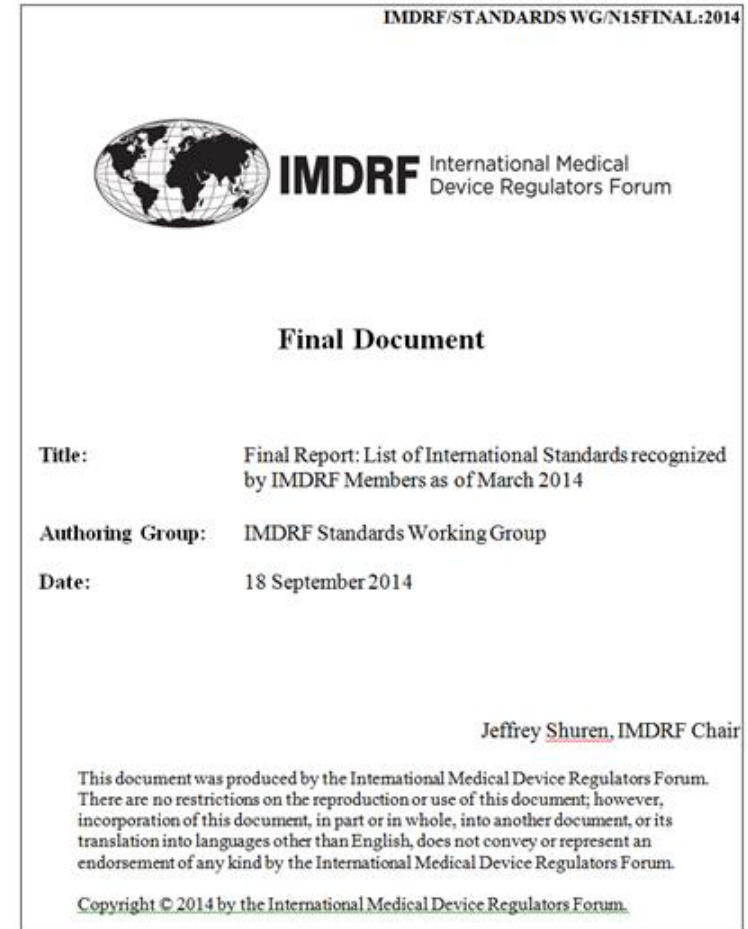
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Number of recognized/mandatory standards in IMDRF jurisdictions

	recognised	partially	mandatory	partially recognised and mandatory
USA	261	33		
EU	222	3		
Canada	181			
Japan	104	105		
Australia	44			
Brasil	102		78	
China	66	71	130	
Russia				239

A list of 1102 IEC and ISO standards relevant to medical devices has been made available.



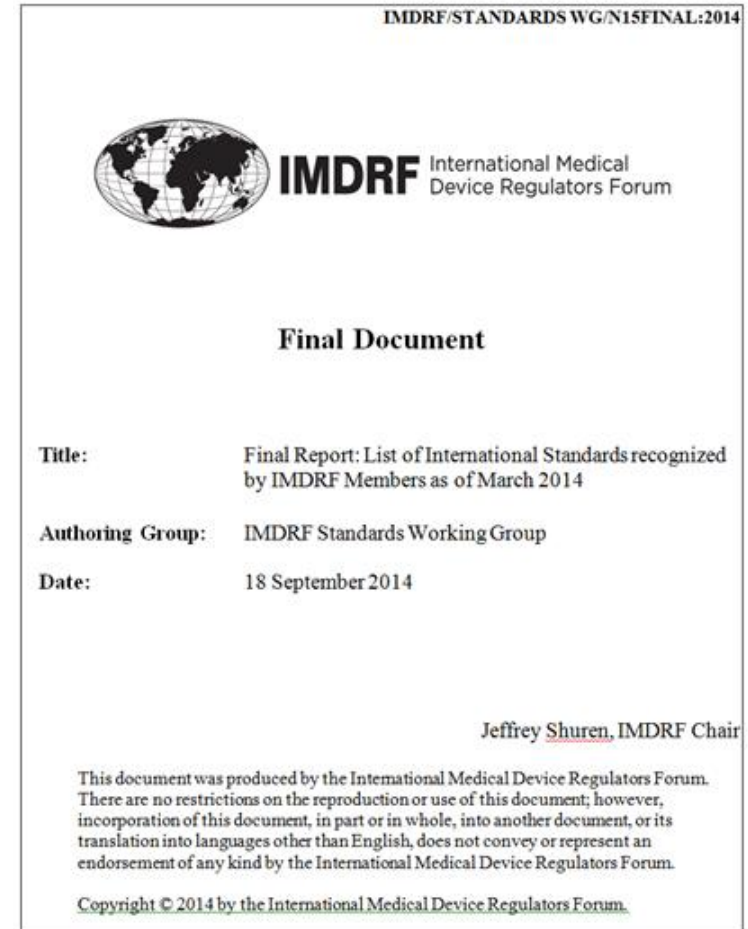
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There are 2 standards which are recognized/mandatory by 7 of the 8 regions

Document reference	Publication ¹	Title
ISO 14630	2008-01	Non-active surgical implants_- General requirements
ISO 14971	2007-03	Medical devices_- Application of risk management to medical devices

¹ Some regions have recognized older versions of standards and are in the process of recognizing updated versions.



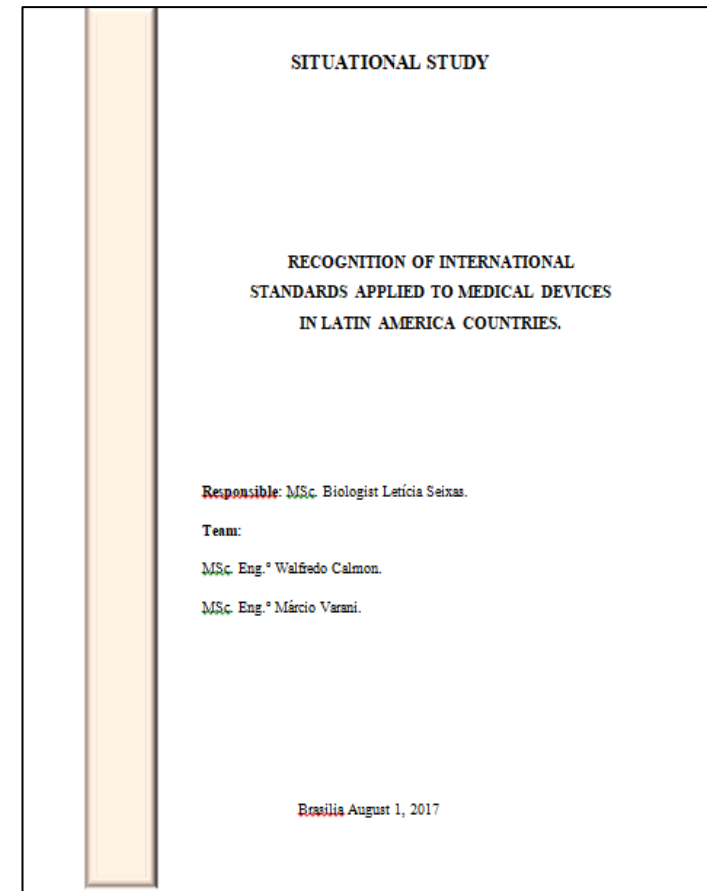
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PROJECT

Objective:

Carry out a study to identify the current situation of the health regulatory systems of Latin American countries, especially in relation with international standards applied to medical devices.

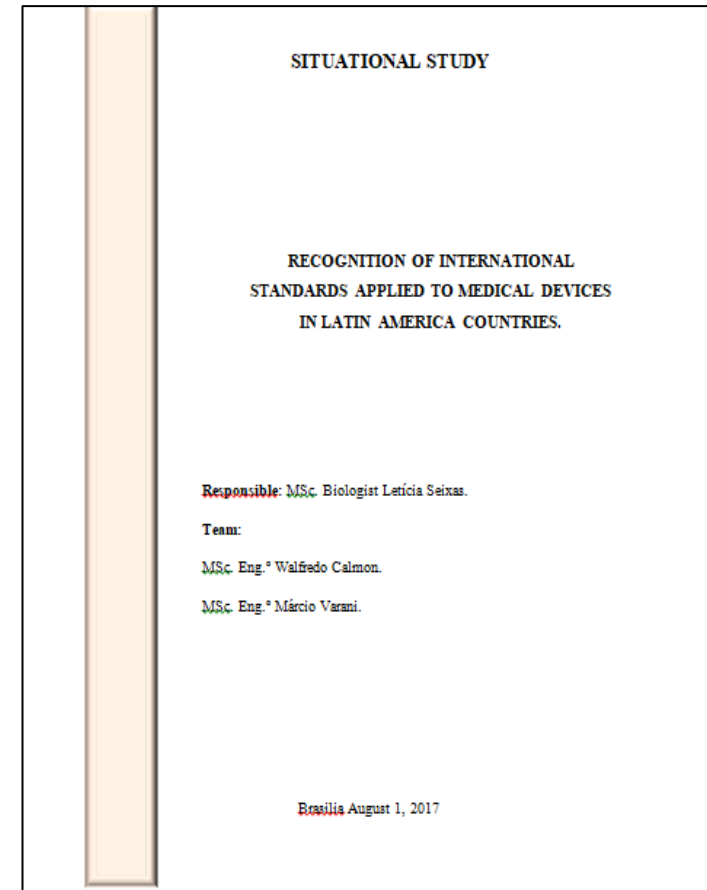


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PROJECT

Methodology:

The project will be developed using a qualitative methodology, which will consist of the application of a questionnaire to the representatives and authorities of Colombia, Costa Rica, Mexico and Peru (Phase I). Other countries will be part of Phase II.



QUESTIONNAIRE



- ✓ Language: Spanish
- ✓ Questions about the regulatory model implemented by the country.
- ✓ List of 245 valid international standards on Medical Devices based on ISO 16142- Medical devices – Recognized essential principles of safety and performance of medical devices

INTERNATIONAL STANDARD **ISO 16142-1**

First edition
2016-03-01

Medical devices — Recognized essential principles of safety and performance of medical devices —
Part 1:
General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards

Dispositifs médicaux — Lignes directrices pour le choix des normes correspondant aux principes essentiels reconnus de sécurité et de performance des dispositifs médicaux



Reference number
ISO 16142-1:2016(E)

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QUESTIONNAIRE



- ✓ ISO 16142- Medical devices -- Recognized essential principles of safety and performance of medical devices
- Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards
- Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards

INTERNATIONAL
STANDARD

ISO
16142-1

First edition
2016-03-01

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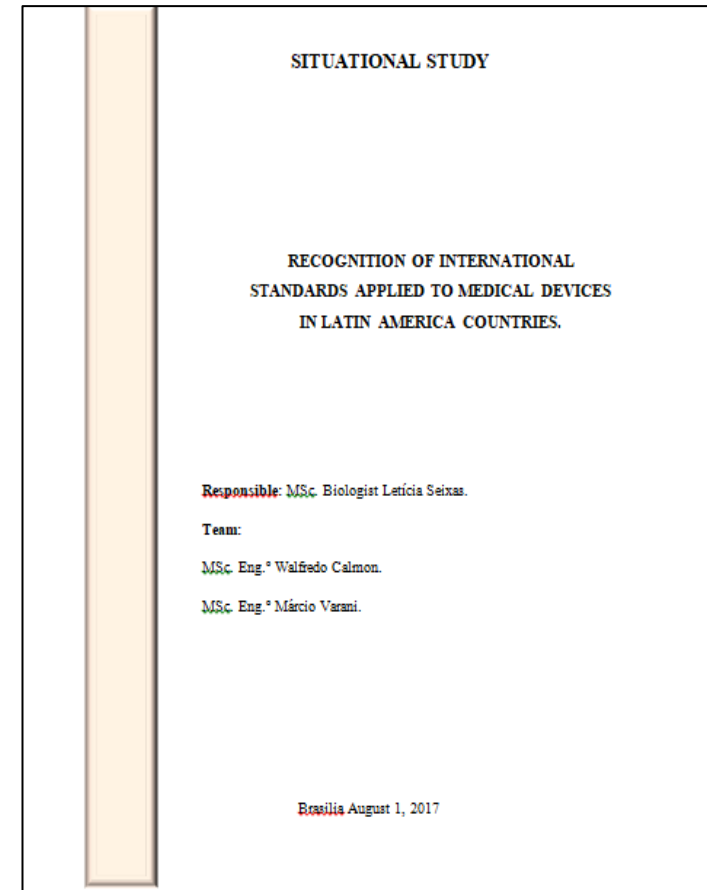
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EXPECTED OUTCOMES

Contribute to the improvement of regulatory systems, especially in relation to the recognition of international standards for regulatory purposes.



TEAM



Leticia Seixas – MSc. Biologist, worked as Manager of In Vitro Diagnostic Products of the National Agency of Sanitary Surveillance (ANVISA) from 2001-2014.

Executive Director from Latin American Alliance for the Development of In Vitro Diagnostics since 2015.



Walfredo Calmon - MSc. Chemical Engineer, worked in the Medical Devices area, at the National Surveillance Agency ANVISA - from 2001 to 2014, and in the Brazilian Ministry of Health - from 2015 to 2016.



Marcio Varani - MSc. Electronic engineer worked as Manager of Materials for Use in Health and Medical Equipment from 2002 to 2014 at the National Surveillance Agency – ANVISA.

SPECIAL COLLABORATION



ALDIME+

LONDON
SCHOOL of
HYGIENE
& TROPICAL
MEDICINE



ALADDIV TEAM





The future is in our hands...



Obrigado!

Letícia Seixas & Carlos Eduardo Gouvêa

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