US Food & Drug Administration

Standards and Conformity Assessment Program

Putting Standards to Work

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MDRC Project: Good Regulatory Practices & Technical Competencies
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Topics

- FDA's Standards and Conformity Assessment Program (S-CAP)
- Standards in device regulatory review
- Accreditation Scheme for Conformity Assessment (ASCA)
- Regulator roles in standards

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THE STANDARDS AND CONFORMITY ASSESSMENT PROGRAM (S-CAP)

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Why Consensus Standards?

- Crowd-sourced, they rely upon broad array of experts and expertise
- Consensus standards preferred over lengthy legal or rule-making approaches
- Encourage innovation and competition among product developers
- Reduce burdens on manufacturers by harmonizing expectations across jurisdictions
- Streamline conformity assessment
- Promote regulatory science at national and international levels

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Regulatory Science and Standards

- Participation by all stakeholders in standards development including - *especially* - regulators
- Standards developers have an understanding of regulatory needs
- Standards are written to accommodate clear testing methods and acceptance criteria

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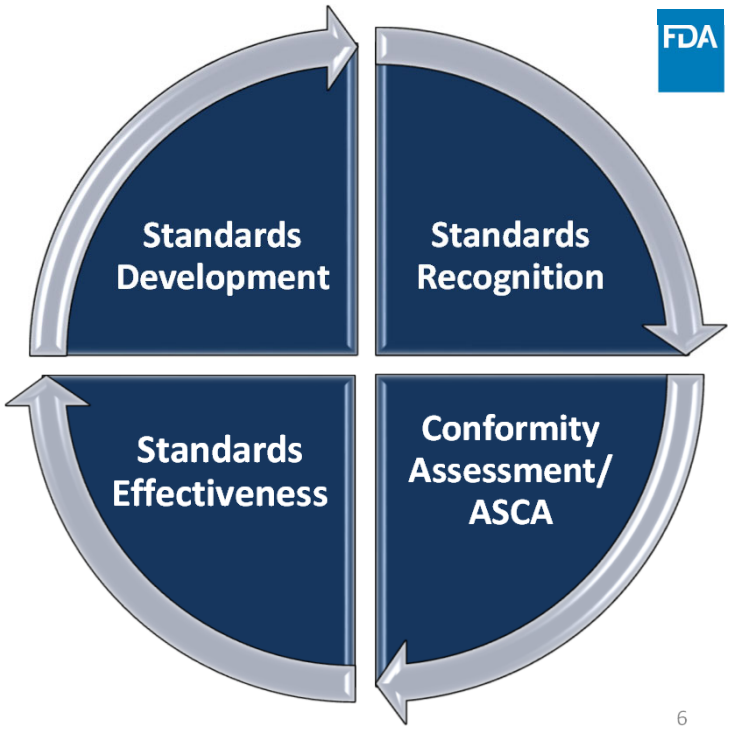
Standards and Conformity Assessment Program (S-CAP)



S-CAP goal: advance the development and use of regulatory-ready standards

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Standards Recognition Program

'Recognition' - FDA's formal identification of a standard after determining that it is appropriate for manufacturers to declare conformance (with a declaration of conformity) to meet relevant requirements.

The FDA:

- Encourages external and internal stakeholders to nominate standards for recognition
- May recognize all, part or none of the standard
- Will publish the decision rationale
- Regularly updates recognition and non-recognition decisions
  - Recognized Consensus Standards Database
  - Non-recognized Consensus Standards Database
- May withdraw recognized standards, as appropriate

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FDA Recognized Consensus Standards Database

Searchable by:

- Standards Development Organization (SDO)
- Designation number
- FDA recognition number
- Keywords
- Inclusion in ASCA
- And more

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/search.cfm

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Supplementary Information Sheets (SIS) include:

- Recognition number
- Date of entry into Recognized Consensus Standards Database
- SDO and designation number
- US identical adoption (if applicable)
- Scope of standard
- Extent of recognition
- Included in ASCA?
- Rationale for recognition or partial recognition
- Transition period (if any)
- Examples of applicable device product codes
- Relevant guidance documents or other publications
- Relevant FDA Specialty Task Group (STG)
- Name of contact person

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Part B: Supplementary Information Sheet (SIS)

FR Recognition List Number 056 **Date of Entry** 06/07/2021

FR Recognition Number 4-278

Standard

ISO 4823 Fifth edition 2021-02
Dentistry - Elastomeric impression and bite registration materials

Scope/Abstract

This document specifies the requirements and their test methods for elastomeric impression and bite registration materials.

NOTE This document does not address possible biological hazards associated with the materials. Assessment of these hazards is addressed in ISO 7405 and the ISO 10993 series.

Extent of Recognition

Complete standard

Rationale for Recognition

This standard is relevant to medical devices and is recognized on its scientific and technical merit and/or because it supports existing regulatory policies.

Transition Period

FDA recognition of ISO 4823 Fourth edition 2015-08 [Rec# 4-225] will be superseded by recognition of ISO 4823 Fifth edition 2021-02 [Rec# 4-278]. FDA will accept declarations of conformity, in support of premarket submissions, to [Rec# 4-225] until July 10, 2022. After this transition period, declarations of conformity to [Rec# 4-225] will not be accepted.

Public Law, CFR Citation(s) and Procode(s)*

Regulation Number	Device Name	Device Class	Product Code
§872.3660	Material, Impression	Class 2	ELW

FDA Technical Contacts

SIS Example (complete recognition)

ISO 4823:2021

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SIS Example

ISO 10942 Third edition 2022-01 (partial recognition)

Note extent of recognition and rationale

Note additional relevant documents

Part B: Supplementary Information Sheet (SIS)

FR Recognition List Number 059 **Date of Entry** 12/19/2022

FR Recognition Number 10-132

Standard

ISO 10942 Third edition 2022-01
Ophthalmic instruments - Direct ophthalmoscopes

Scope/Abstract

This document, together with ISO 15004-1 and ISO 15004-2, specifies minimum requirements and test methods for hand-held direct ophthalmoscopes designed for directly observing the eye fundus.

This document takes precedence over ISO 15004-1 and ISO 15004-2, if differences exist.

Extent of Recognition

Partial recognition. The following part(s) of the standard is (are) not recognized:

Any reference to ISO 15004-2 in the standard

Rationale for Recognition

This standard is relevant to medical devices and is recognized on its scientific and technical merit and/or because it supports existing regulatory policies.

This standard is recognized in part because:
Reference to ISO 15004-2 for light hazard protection is in conflict with another FDA-recognized standard (See ANSI Z80.36-2021, reference #2 listed below). FDA has replaced ISO 15004-2 with ANSI Z80.36 as the recognized standard for light hazard protection in ophthalmic instruments.

Transition Period

FDA recognition of ISO 10942 Second edition 2006-06-01 [Rec# 10-37] will be superseded by recognition of ISO 10942 Third edition 2022-01 [Rec# 10-132]. FDA will accept declarations of conformity, in support of premarket submissions, to [Rec# 10-37] until December 17, 2023. After this transition period, declarations of conformity to [Rec# 10-37] will not be accepted.

Public Law, CFR Citation(s) and Procode(s)*

Regulation Number	Device Name	Device Class	Product Code
§886.1570	Ophthalmoscope, Battery-Powered	Class 2	HLJ
§886.1570	Ophthalmoscope, Laser, Scanning	Class 2	MYC
§886.1570	Ophthalmoscope, Ac-Powered	Class 2	HLI

Relevant FDA Guidance and/or Supportive Publications*

1. Guidance for Industry Ophthalmoscope Guidance - (Direct and Indirect), issued July 1998.

2. ANSI Z80.36-2021 Ophthalmics - Light Hazard Protection for Ophthalmic Instruments.

Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices - Guidance for Industry and Food and Drug Administration Staff, issued September 2018.

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STANDARDS IN DEVICE REGULATORY REVIEW

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Using FDA-Recognized Standards

FDA strongly encourages the use of recognized standards in premarket submissions

Declarations of conformity are used with recognized standards, reducing the documentation submitted to FDA

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Using Consensus Standards

- Voluntary
  - Only mandatory if cited in regulation ('incorporated by reference')
- In any type of submission
  - PMA, 510(k), etc.
- With a DOC (recognized standards only) or 'General Use' (any standards, recognized or not)

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Declaration of Conformity (DOC)

- Attestation that the device conforms with the cited FDA-recognized standard
- If the manufacturer declares conformity with a recognized standard, a DOC accompanies the submission
- DOCs generally reduce the documentation needed to be included – ***and reviewed*** - in a submission

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'General Use' of Standards

Choose 'General Use' when citing:

- Non-recognized standards
- A recognized standard without submitting a DOC
- A recognized standard where deviations have been made to the methodology

**** For General Use, complete test reports should be submitted - *and will be reviewed* ****

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THE ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT (ASCA)

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What is ASCA?

- Capitalizes on voluntary consensus standards in device development and review
- 'Puts standards to work' in conformity assessment
- *ASCA Accreditation* from FDA to qualified test labs means:
  - Confidence in their methods and results
  - No need for complete test report review

ISO/IEC 17011:2017
Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies

← Popular standards

ISO/IEC 17025
Testing and calibration laboratories

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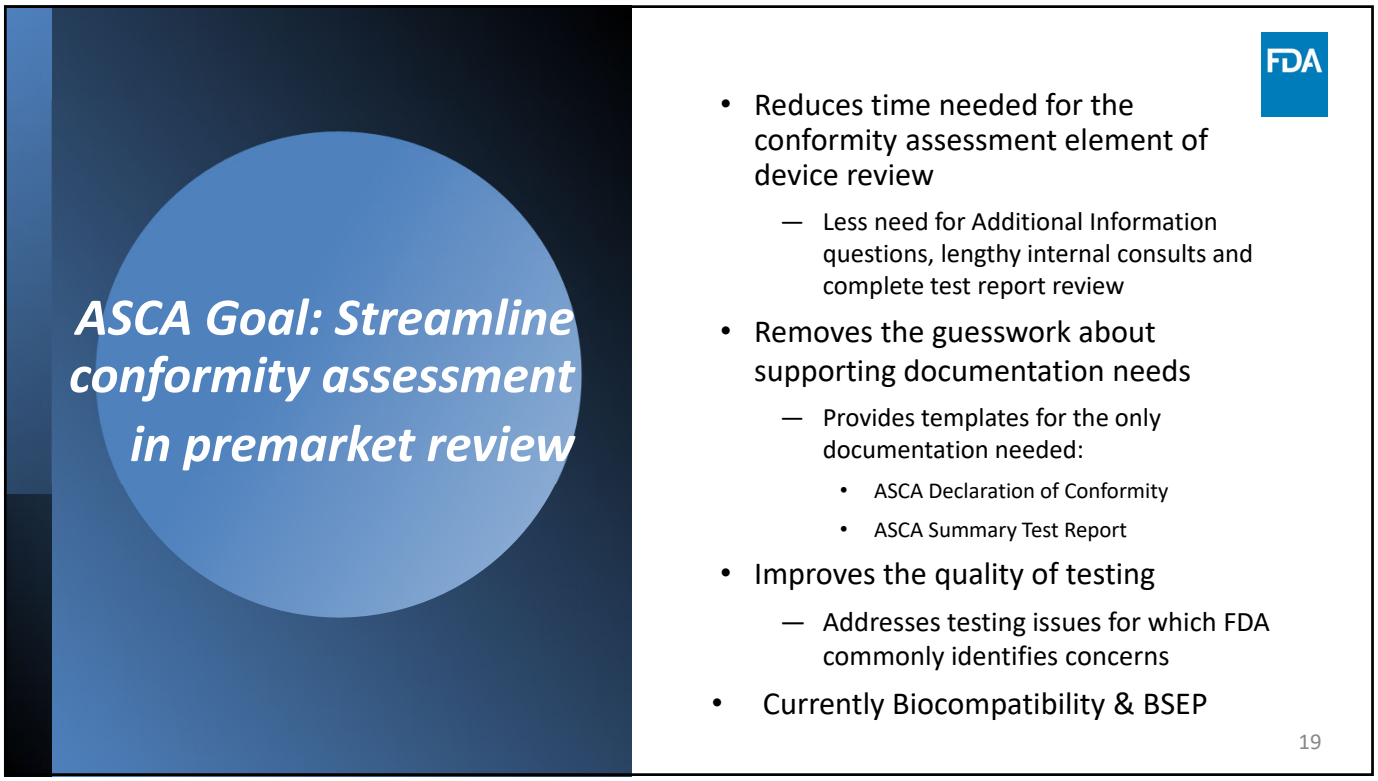
ASCA Goal: Streamline conformity assessment in premarket review
FDA
• Reduces time needed for the conformity assessment element of device review
— Less need for Additional Information questions, lengthy internal consults and complete test report review
• Removes the guesswork about supporting documentation needs
— Provides templates for the only documentation needed:
• ASCA Declaration of Conformity
• ASCA Summary Test Report
• Improves the quality of testing
— Addresses testing issues for which FDA commonly identifies concerns
• Currently Biocompatibility & BSEP
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FDA
REGULATOR ROLES IN STANDARDS
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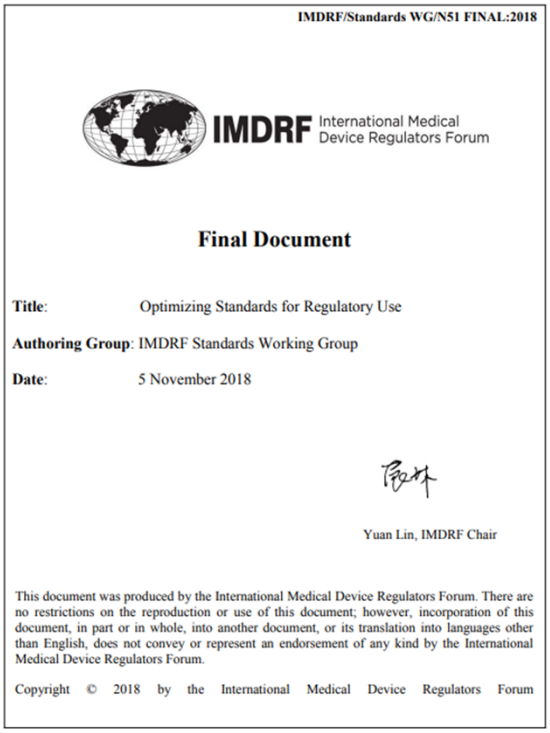
IMDRF International Medical Device Regulators Forum

Guidance Recommendations:

- Standards must be improved for regulatory use
- IMDRF members should participate as early as possible in standards development



IMDRF/Standards WG/N51 FINAL:2018

IMDRF International Medical Device Regulators Forum

Final Document

Title: Optimizing Standards for Regulatory Use

Authoring Group: IMDRF Standards Working Group

Date: 5 November 2018

Yuan Lin, IMDRF Chair

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FDA

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Challenges to Regulatory-ready Standards

FDA

IMDRF Standards Working Group identified:

- *Poor participation by RAs* → can lead to the development of standards that do not include substance and language that are useful for regulatory purposes
- *Unbalanced representation* → can result in some groups' disproportionate voice in and impact on standards development
- *Content of standards can be too flexible/unclear* → can render standards less useful as they may not adequately identify minimum requirements for quality, safety and/or effectiveness/performance.

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Optimizing Standards

- Standards should feature:
  - Clear scope
  - Strong rationale that:
    - Explains the requirements and identifies test methods and/or other means of demonstrating compliance
  - Identification of risk and direction on how to address it
  - Terms and definitions established and accepted in other standards
  - Means to assess clinical performance (if applicable) as part of the normative requirements

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Optimizing Standards

- Standards should feature (continued):
  - Clear and quantitative acceptance criteria
  - If acceptance criteria is not mandatory/present, a justification for why, and how to demonstrate conformance to the standard
  - Well-accepted and verified test methods
  - Transparent and clear (e.g., 'track changes') revisions
  - An annex or table that cross references the standard's clauses to the IMDRF *Essential Principles of Safety and Performance*

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Regulator roles in standards

- Clear expectation on how standards use supports regulatory requirement(s)
- Harmonized approach to adoption of standard
  - Complete adoption vs. partial
  - Transition period between versions
  - Voluntary vs. mandatory use
- Understanding on how conformity assessment results are accepted within a specific jurisdiction to supports global harmonization

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Enhancing Participation

- Regulatory Authorities should build a strong standards program that encourages contributions to standards development
- Engagement with SDOs is essential
- Contribute regulatory perspective
- Support harmonized regulatory objectives
- Get involved early
- Consider leadership roles

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Join the Standards Conversation

- Nations (through their 'national bodies' or 'national committees') are ISO and IEC members; they appoint individuals to represent them
- National bodies are responsible for ISO and IEC work within their countries
- National bodies appoint national or 'mirror' committees (called TAGs in the US) whose work mirrors that of the ISO and IEC bodies
  - Develop consensus on issues
  - Review proposals and documents
  - Comment on new standards
- Regulators should participate at both the national (for example, national bodies or mirror committees) and the international levels (ISO and IEC committees)
  - Goal: build regulatory interests into the standards (e.g., test methods, acceptance criteria)
  - Submit effective comments

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Summary

- S-CAP advances the development and use of regulatory-ready standards
- Consensus standards are an invaluable tool to improve device quality and promote global harmonization
- A conformity assessment program like ASCA can streamline device review and enhance the quality of testing
- Regulators should build a strong standards program and participate in standards development

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FDA Standards Resources

- **Standards & Conformity Assessment Program**
  www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program#intro
- **FDA Recognized Consensus Standards Database**
  www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

Email: **CDRHStandardsStaff@fda.hhs.gov**

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FDA Relevant Guidances

- **Recognition and Withdrawal of Voluntary Consensus Standards guidance**
  www.fda.gov/regulatory-information/search-fda-guidance-documents/recognition-and-withdrawal-voluntary-consensus-standards
- **Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices guidance**
  www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices
- **Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions: Guidance for Industry and Food and Drug Administration Staff**
  https://www.fda.gov/media/113230/download

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FDA ASCA Resources

- **ASCA web page**
  www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca
- **ASCA program guidance**
  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program
- **ASCA Standards-specific guidances**
  - **Basic Safety and Essential Performance standards-specific guidance:**
    https://www.fda.gov/regulatory-information/search-fda-guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment-medical-electrical-systems-and
  - **Biocompatibility standards-specific guidance:**
    https://www.fda.gov/regulatory-information/search-fda-guidance-documents/biocompatibility-testing-medical-devices-standards-specific-information-accreditation-scheme
- **Ask ASCA! ASCA@FDA.HHS.GOV**

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International Resources

- **IMDRF *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices: 2018***
  http://imdrf.org/docs/imdrf/final/technical/imdrf-tech-181031-grrp-essential-principles-n47.pdf
- **IMDRF *Optimizing Standards for Regulatory Use* guidance:**
  http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-181105-optimizing-standards-n51.pdf
- **International Electrotechnical Commission (IEC)**
  http://www.iec.ch/about/activities/standards.htm?ref=home
- **International Organization for Standardization (ISO)**
  https://iso.ch/home.html
- **ISO Conformity Assessment tools to support public policy: the CASCO Toolbox**
  https://www.iso.org/sites/cascoregulators/02_casco_toolbox.html
- **ISO/IEC Directives Parts 1 (Ed. 13, 2017) and 2 (Ed. 7, 2016)**
  https://www.iec.ch/members_experts/refdocs/iec/isoiecdir-1-consolidatedIECsup%7Bed13.0%7Den.pdf
  https://www.iso.org/sites/directives/current/part2/index.xhtml
- **GHWP WG8 - AHWP/WG2-WG8/F002:2014 Role of Standards in the Assessment of Medical Devices**
  http://www.ahwp.info/sites/default/files/2017-07/Final_GHWP_WG2_WG8_F002_2014.pdf

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International Resources, cont'd

- **ISO/IEC Guide 59, ISO and IEC recommended practices for standardization by national bodies 2019**
  https://www.iso.org/standard/71917.html
- **ISO/IEC Guide 63:2012 Guide to the development and inclusion of safety aspects in International Standards for medical devices**
  https://www.iso.org/standard/50729.html
- **ISO/IEC 17007:2009, Conformity assessment – Guidance for drafting normative documents suitable for use for conformity assessment**
  https://www.iso.org/standard/42635.html
- **ISO/IEC 17050-1:2004 Conformity Assessment – Supplier's Declaration of Conformity – Part 1: General Requirements**
  https://www.iso.org/standard/29373.html#:~:text=ISO%2FIEC%2017050%2D1%3A2004%20specifies%20general%20requirements%20for,irrespective%20of%20the%20sector%20involved.
- **ISO/IEC 17050-2:2004 Conformity Assessment – Supplier's Declaration of Conformity – Part 2: Supplemental Information**
  https://www.iso.org/standard/35516.html
- **ISO 14971:2019 Medical devices – Application of risk management to medical devices**
  https://www.iso.org/standard/72704.html
- **Society for Standards Professionals**
  https://www.ses-standards.org/page/A2?
- **World Health Organization WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices 2017**
  https://apps.who.int/iris/handle/10665/255177
- **World Trade Organization Agreement on Technical Barriers to Trade 1994**
  https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

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U.S. FOOD & DRUG ADMINISTRATION

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