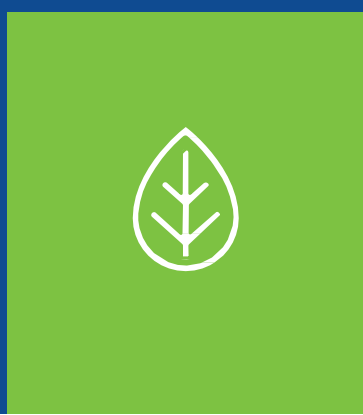
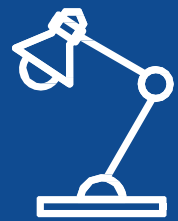


ISO/TC 210/STTF

Spanish Translation Task Force of ISO/TC 210

Quality management and corresponding
general aspects for medical devices



***TC 210 Quality management and
corresponding general aspects for medical devices***

**WG 1 - Application of quality
systems to medical devices**

**WG 5 - Connectors for
reservoir delivery systems**

**WG 2 - General aspects stemming from the
application of quality principles to medical devices**

**WG 6 - Application of post
market surveillance systems to medical devices**

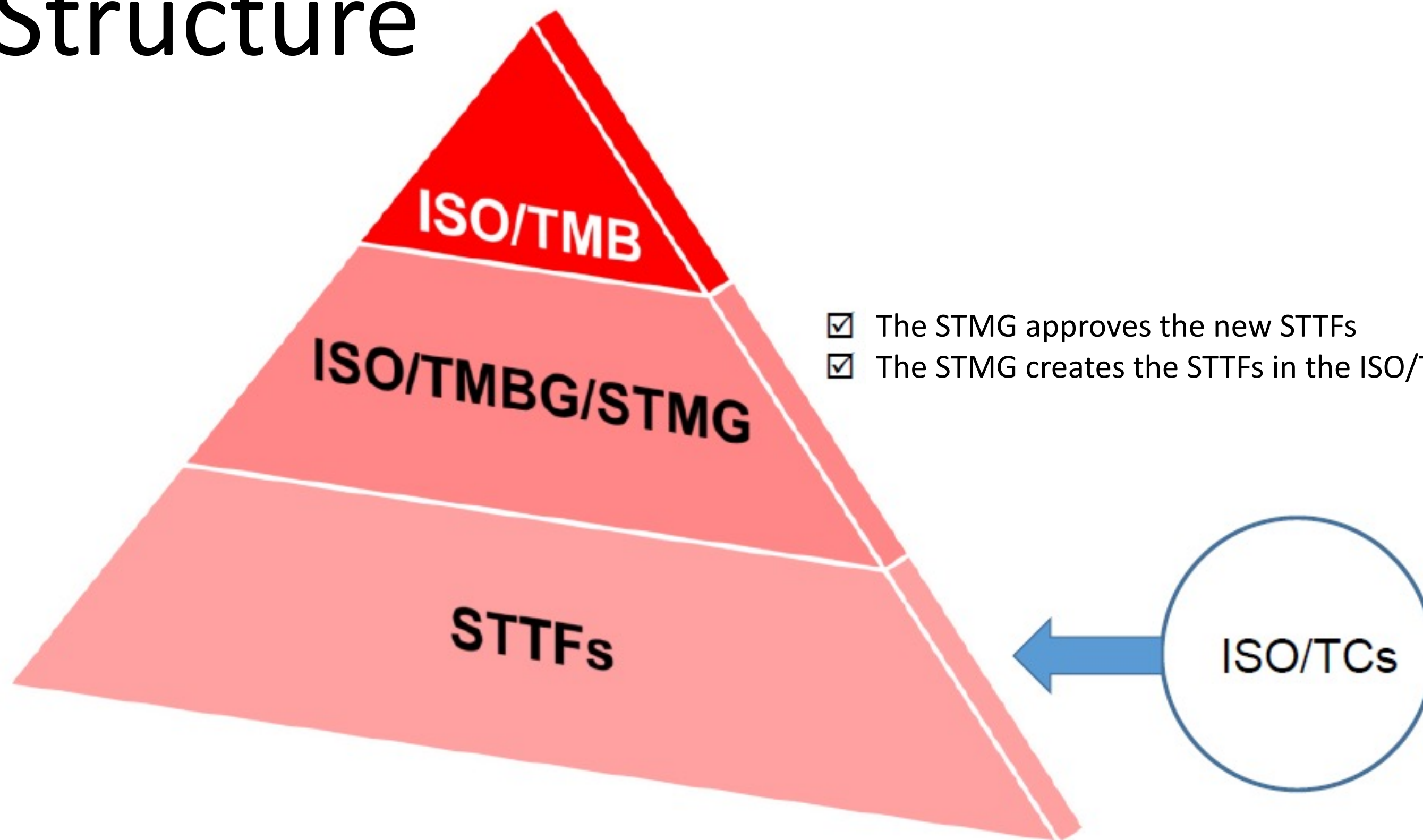
**WG 3 - Symbols and
nomenclature for medical devices**

**WG 7 - Good engineering
maintenance management**

STTF - Spanish translation task force



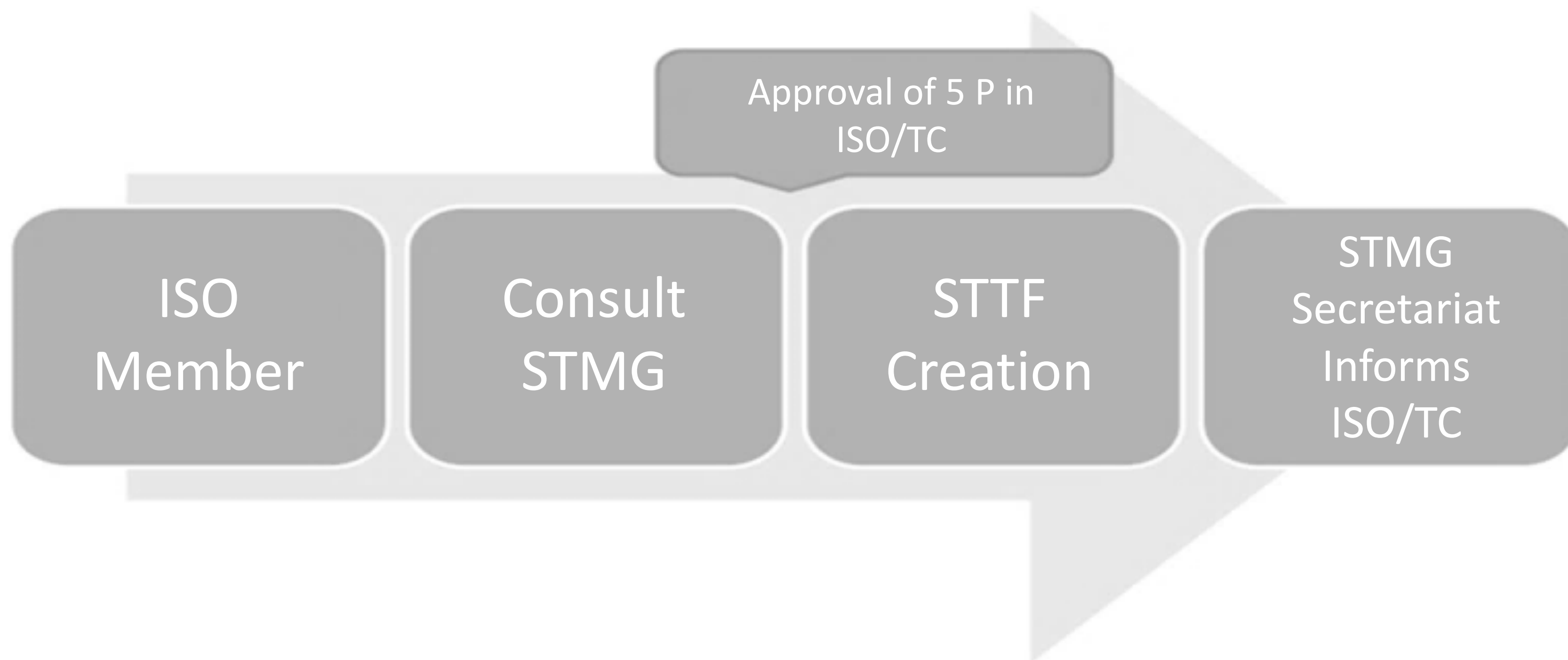
Structure



- ☑ The STMG approves the new STTFs
- ☑ The STMG creates the STTFs in the ISO/TC structure

Initiative to develop ISO standard in Spanish in a new ISO/TC

Objective: ISO Standard Publication in Spanish



Objectives of the STTF's

- ❖ **Only Spanish** version available to all NNOs, based on consensus.
- ❖ Contribution to **more agile** national adoptions
- ❖ **Increased use** of ISO/TC normative documents.
- ❖ Helps countries generate technical critical mass at stages of the document in English **prior to publication** (the most relevant documents begin their translation in the DIS phase).
- ❖ **Cohesion** of the **Spanish-speaking** community

ISO/TC 210 STTF – Spanish Translation Group

Full Members (11 countries, 26 experts actively participating):

- Argentina
- Bolivia
- Colombia
- Costa Rica
- Cuba
- Ecuador
- Spain
- Guatemala
- Mexico
- Panama
- Dominican Republic

Observers: United Kingdom and United States of America

Introduction

“Medical Device” Concept:

National regulations in Spanish use concepts as:

- Medical devices
- Medical equipment
- Medical products
- Sanitary product

The scope of the concept “medical device” can vary between one country and another, and from one region to the next

The concept “medical device” has been translated through consensus as “dispositivo médico/product sanitario” (MD).

Proposed work plan:

- ❖ ISO/TR 24971:2020 Medical devices – Orientation for submission of ISO 14971:2019.
(In progress)
- ❖ ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements.
- ❖ ISO/TR 20416:2020 Medical devices — Post-market surveillance for manufacturers.
- ❖ ISO 20417:2021 Medical devices – Information to be supplied by the manufacturer.

<https://www.iso.org/obp/ui>



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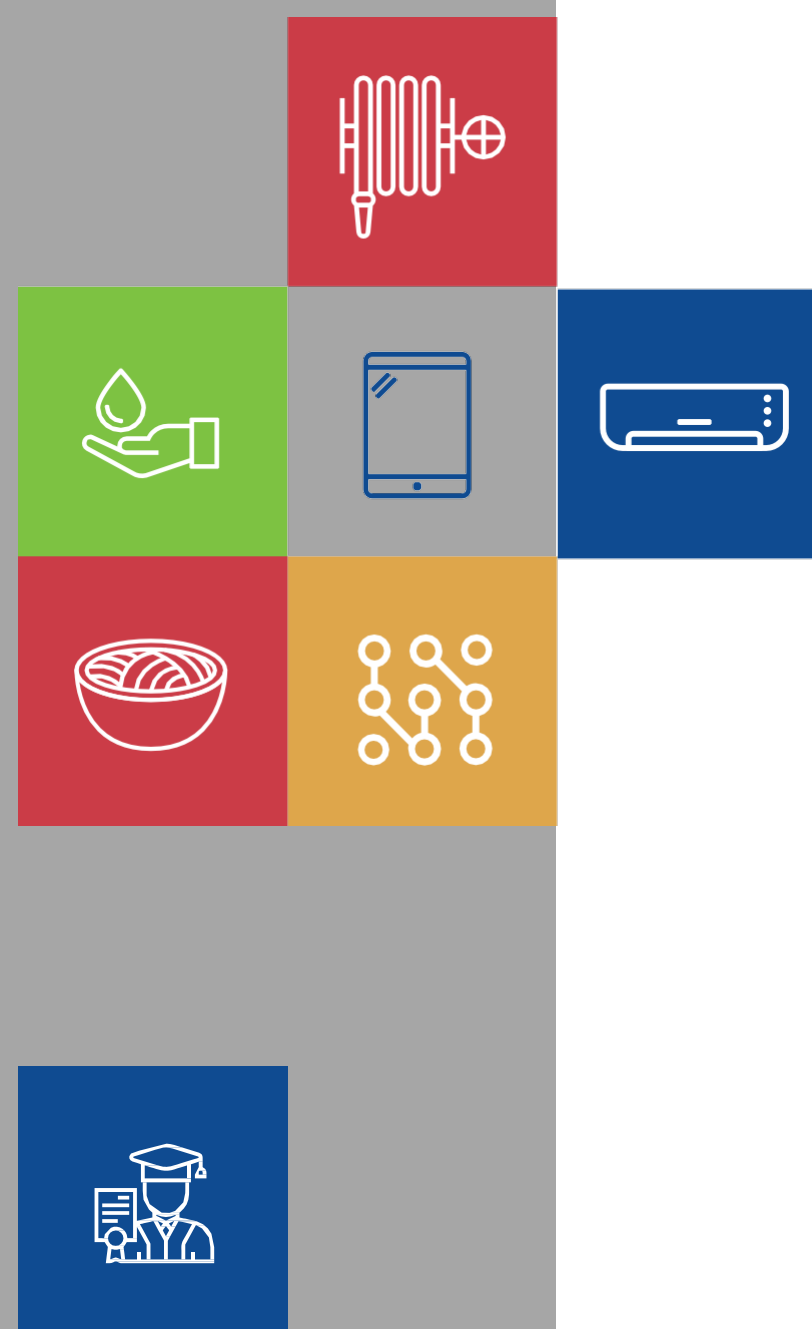
Spanish 1

Committees >

Technical sector >

| | | | |
|---|--|---|---|
| 1 |  | <p>ISO 14971:2019(es) Dispositivos médicos/productos sanitarios (MD) — Aplicación de la gestión del riesgo a los MD <small>Medical devices — Application of risk management to medical devices</small></p> <p>Prólogo ...práctica médica . Esta tercera edición anula y sustituye a la segunda edición (ISO 14971:2007) que ha sido revisada técnicamente. Los cambios principales, comparados con la edición... 14971...</p> <p>3.20 evaluación del riesgo ...versión en español: Durante el estudio de la versión en español de la Norma ISO 14971 se identificó que, en la versión en inglés, donde dice (3.20) debe...</p> <p>See 7 more</p> | <div style="background-color: #0070c0; color: white; padding: 5px; text-align: center; width: 40px; margin: 0 auto;">BUY</div> <p><input type="checkbox"/> FOLLOW</p> |
|---|--|---|---|

Thank you!



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