

Impact of technical standards on the health sector (medical devices)

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ICONTEC

National Standardization Agency of Colombia, authorized under national decree.

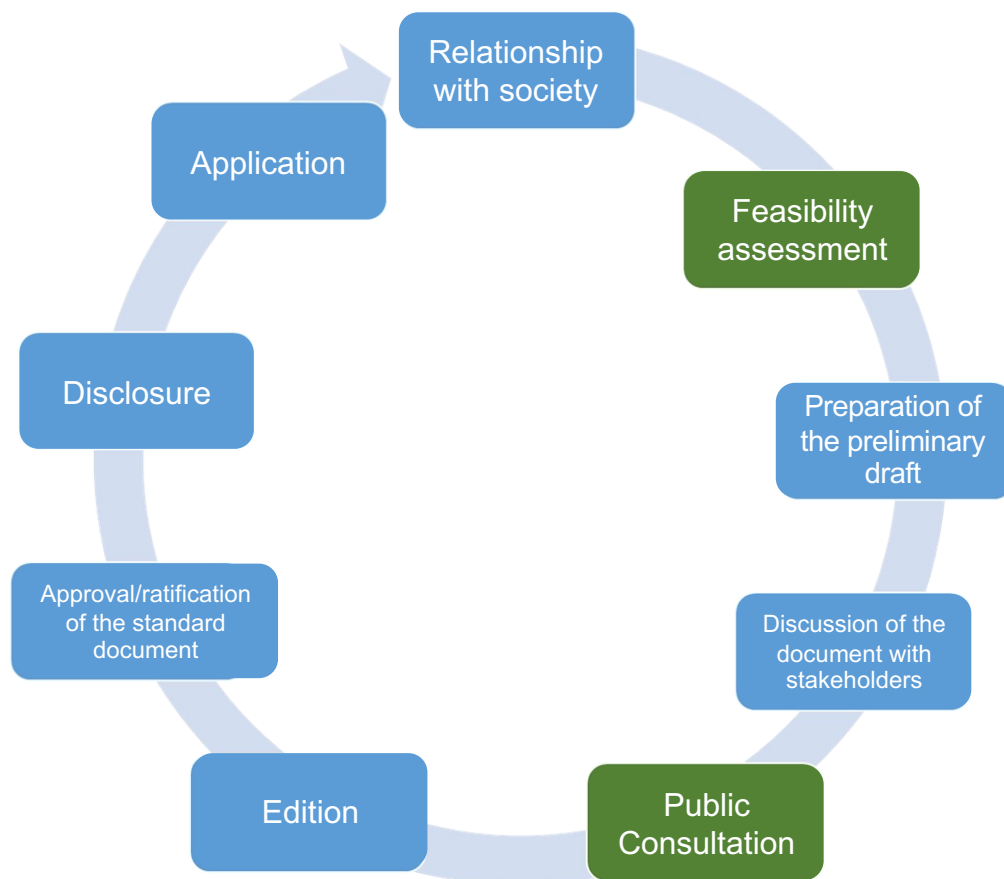
At the directorate of standardization, we have more than 200 technical committees on various sectors.



Technical committee	Chairman	ISO
Medical devices	INVIMA	P – TC 210
Hospital sterilization	3M Colombia	P – TC 198
Hospital disinfectants	Johnson & Johnson	-
Health Biotechnology	Javeriana University	P – TC 276
Patient Safety	Mayor Mederi Hospital	-
Health management	Country Clinic	-
Health Informatics	Del Valle University	O – TC 215
Clinical laboratories	Antioquia University	P – TC 212

Stakeholder diversity – and multilaterality in policy needs

Technical standardization process





PROYECTOS EN CONSULTA

Aquí encontrará los documentos que se encuentran en estudio para que opine sobre ellos. Con su opinión aporta al desarrollo de la normalización y a la competitividad del país.

Macro-Sectores

Comités Técnicos

ICS

01 Agro y alimentos - (9 Consulta(s))	<input type="checkbox"/>
02-2 Industria (Químico) - (7 Consulta(s))	<input type="checkbox"/>
02-3 Industria (Metalurgia) - (7 Consulta(s))	<input type="checkbox"/>
02-4 Industria (Maquinaria y equipos) - (10 Consulta(s))	<input type="checkbox"/>
03 Minería, Petróleo y Gas - (2 Consulta(s))	<input type="checkbox"/>
04 Energético - (1 Consulta(s))	<input type="checkbox"/>
05 Construcción e ingeniería - (15 Consulta(s))	<input type="checkbox"/>
06 Educación - (1 Consulta(s))	<input type="checkbox"/>



Estrategia

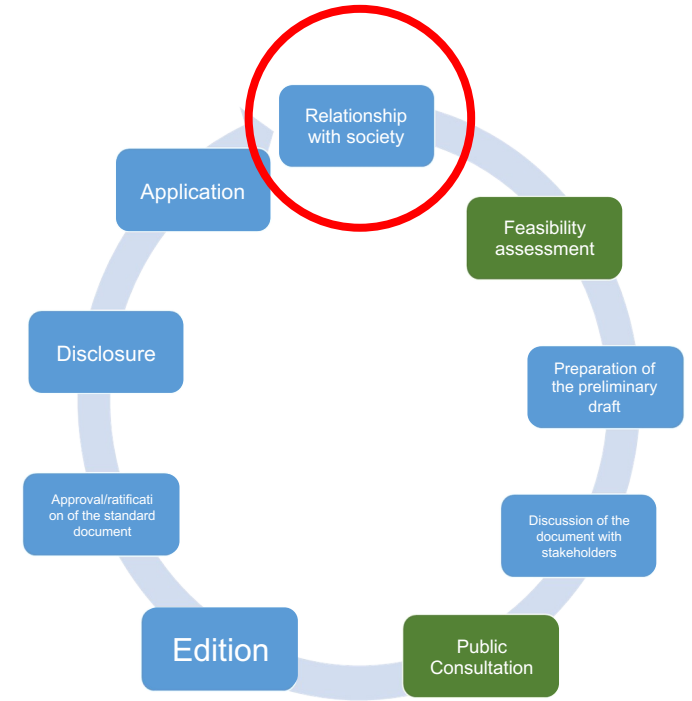
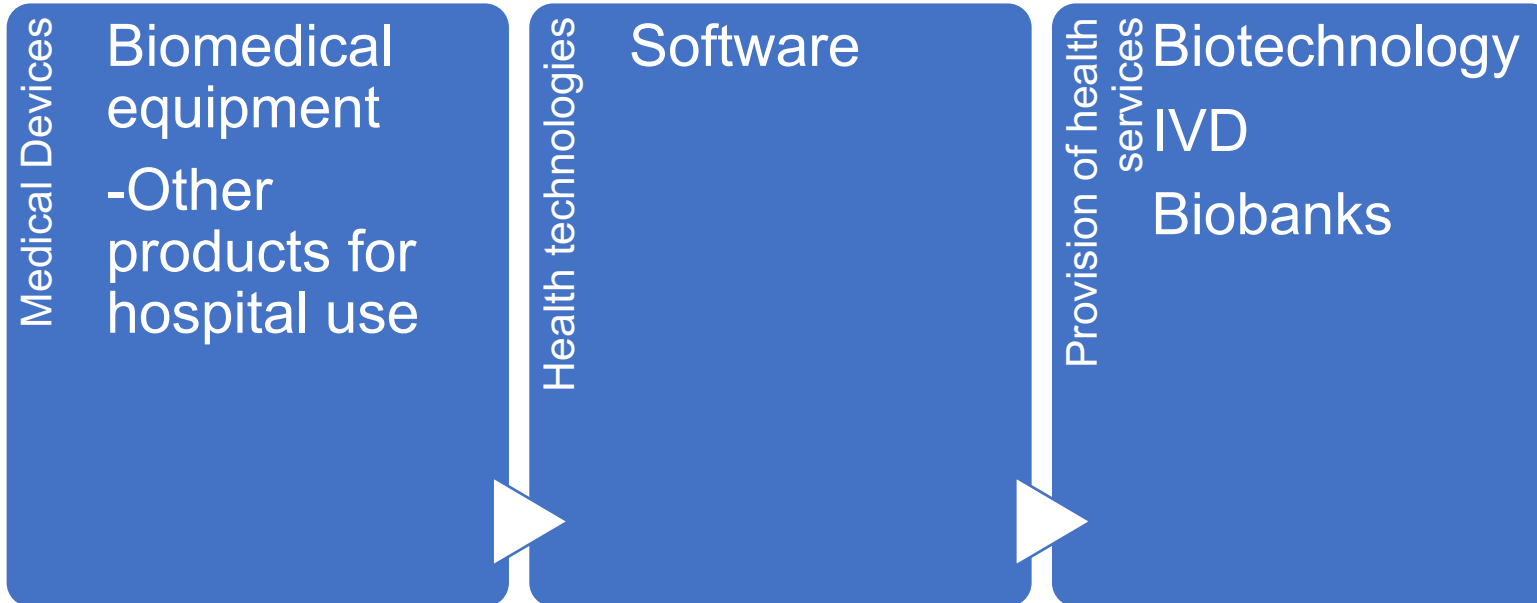
La estrategia de normalización guía el rumbo del país en esta materia. Lo invitamos para que con su opinión contribuya a la definición de este importante documento.

[Evaluar](#)

Technical standards for medical devices and health technologies

According to the sector needs:

- **Feasibility**
- **External / internal**



More than **400** technical standards published within the **MEDICAL DEVICES** framework.

Contribution to Colombian regulation

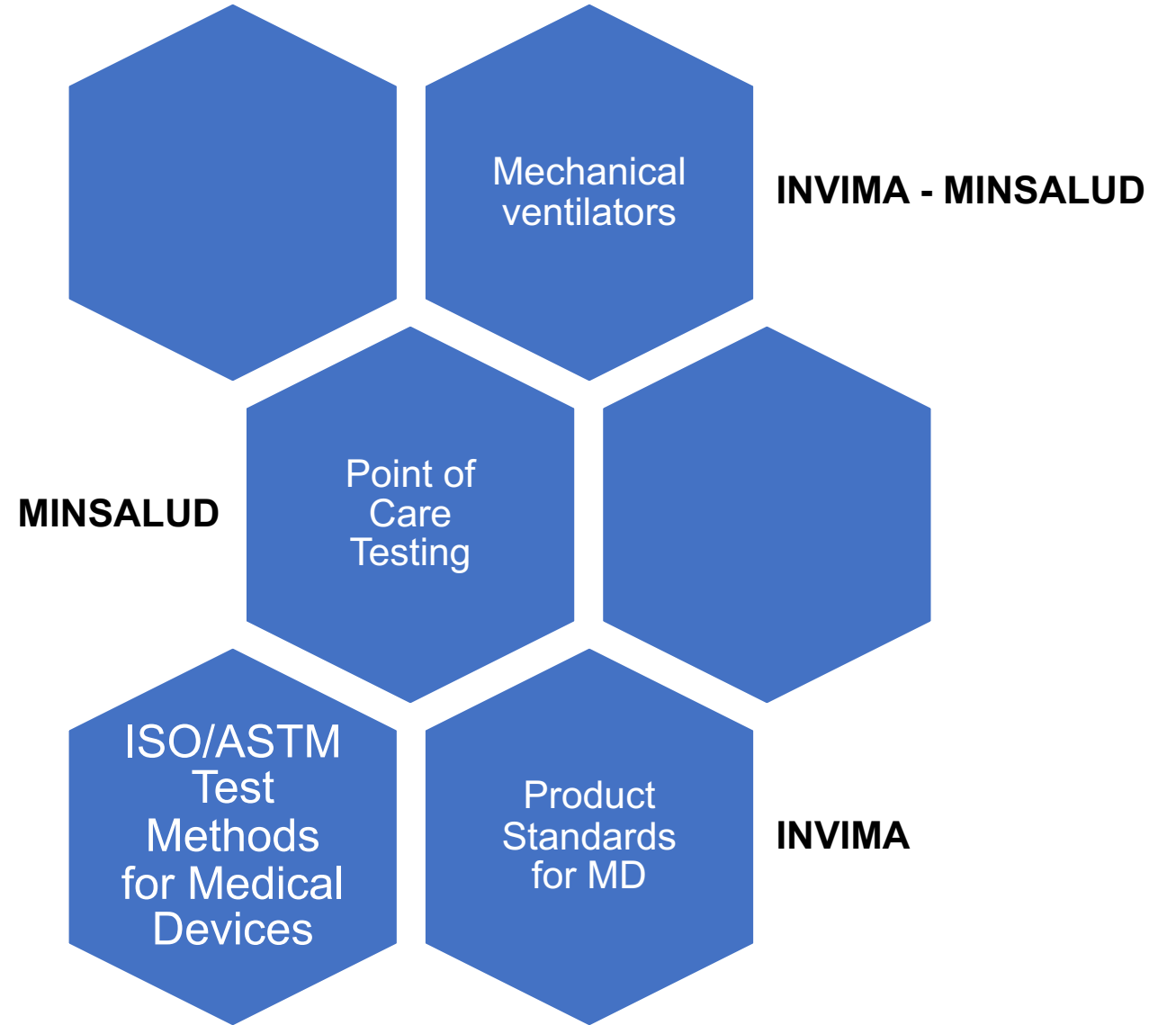
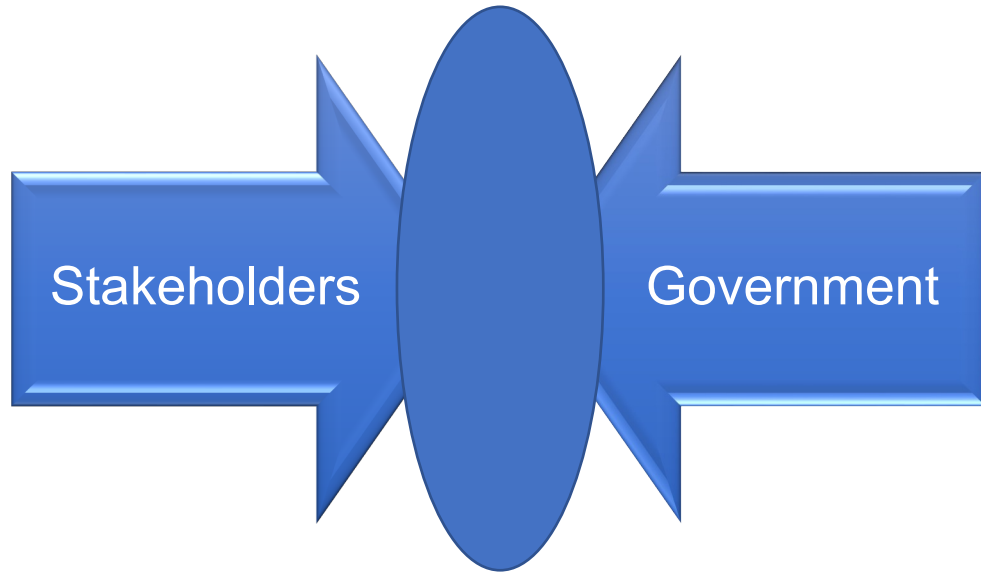
Medical
devices

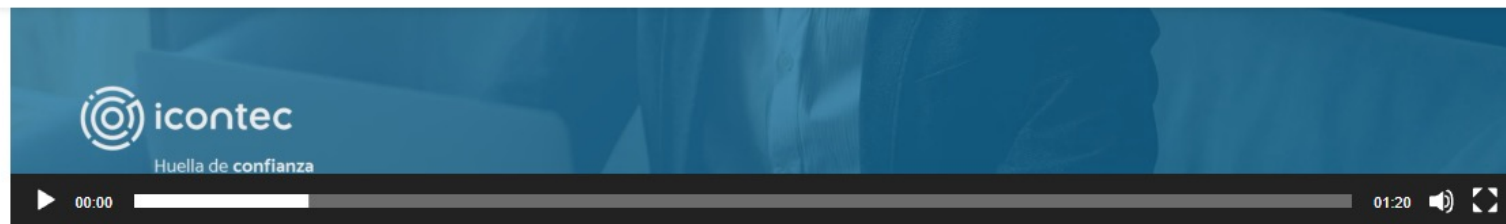
Identical international
adoptions

Participation in ISO TC
210/276/212

Government – industry
– academy interaction

Successful cases





- Dispositivos médicos
- Infraestructura y dotación
- Bioseguridad
- Equipos de protección y seguridad
- Continuidad y recuperación en las empresas
- Productos para desinfección
- Métodos de ensayo
- Servicios de apoyo para atención de pacientes

Para conocer el listado de normas por categoría, [haga clic aquí](#)

Standards available to the community:

Below are the rules that ICONTEC shares with the community to support the management of the crisis generated by COVID-19

MEDICAL DEVICES	
STANDARD	TITLE
NTC 5427:2017	Clinical analysis. Reagents for use in in vitro diagnostics. Conservation of the cold chain and conditions of temperature, storage, transport and distribution.
NTC 6169:2016	Reagents for in vitro diagnosis. Evaluation of the stability of reagents for in vitro diagnostics g
NTC 6097:2014	Elimination or reduction of the risk of infection related to in vitro diagnostic reagents
NTC 1733:2020	Surgical masks. Requirements and test methods
NTC 6436	Standardized specification for the performance of materials used in medical masks
NTC 6435	Standard practice for respiratory protection
NTC-ISO 14155:2020	Clinical research of medical devices for human subjects. Good clinical practice
NTC-ISO 14971:2020	Medical devices. Applying Risk Management to Medical Devices
NTC-ISO 13485	Medical devices. Quality management. Requirements for regulatory purposes

Thank You!