



Optimized standards to support essential principles of safety and performance of medical devices

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Why the drafting of international medical device standards directly impact the harmonisation of standards under the EU legislation?



Recap: the EU New Approach (including medical devices and IVD)

- Presumption of conformity through harmonized standards.
- References published in the Official Journal of the EU.
- Annex Z of the standard.



Harmonised standards under EU Medical Device Directives/Regulations

- **approx. 300 harmonised standards** under Medical Device Directives
- Updates required for the new Regulations: new request (mandate) to be agreed with Member States and standardisation organisations once new principles for mandates have been resolved.
- Work already launched.

What types of standards can be harmonized in the EU?

- *European standards that has been subject to a mandate (request) to the European standardisation organisations*
- ***the standard must be 'suitable' for harmonisation***
 - ⇒ to whom is it addressed?
 - ⇒ what is the scope?
 - ⇒ why is the harmonisation needed?
- ***scope of coverage of ER***
 - ⇒ full – partial
 - ⇒ general – collateral – product specific
 - e.g. 60601-X-X family: a single standard (whichever category) cannot provide for Presumption of Conformity on its own – this needs to be clearly stated in the standard / Annex Z

The role of international standards in harmonisation

- The European standards for medical devices are in general based on international ISO/IEC standards
- Agreements between CEN-ISO and CENELEC-IEC

How to make the international standards fit for EU harmonisation purposes

- International standards made to fit regulatory requirements of multiple jurisdictions:
- EU and other IMDRF members base their legislation on IMDRF documents
 - ✓ = use IMDRF essential principles (EP) as starting point. Make explicit which.
 - ✓ = use terms and definitions from IMDRF and established and accepted in other standards
 - ✓ = explain (rationale) the context - how the standard can be used for demonstrating compliance with EP (including ref. to test methods if applicable)
 - ✓ = identify residual risks not covered
 - ✓ = identify how to mitigate risks/hazards or give directions on how to address them
 - ✓ = associated with acceptance criteria (quantitative, clinical performance etc., generally accepted, validated) – justifications when not applied
 - ✓ = when needed refer to test methods (sufficient detail and verified)
 - ✓ = annex with cross references to IMDRF EP(s)
- Revisions in TC



More reading

The IMDRF Standards Working Group document:

Optimizing Standards for Regulatory Use

(available on the IMDRF website)