STANDARDISATION FOR MEDICAL DEVICES

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REGUALATORY AFFAIRS IN DAY TO DAY LIFE – THE VISIBLE EFFECT OF COMPLIANCE

The CE Mark

Product Labelling: language(s) of the country to be implemented

Growing importance of standards compliance

Vigilance and liability: manufacturers are responsible and need to have a strong traceability system in place, in collaboration with their distributors

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DIRECTIVES FOR MEDICAL TECHNOLOGY

MDD :93/42/EEC

AIMD : 90/385/EEC

IVD : 98/79/EC

Machinery Directive 98/37/EC

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WHAT IS A STANDARD?

A technical specification or other document available to the public, drawn up with the cooperation and consensus or general approval of all interested parties affected by it, based on the consolidated results of science, technology and experience, aimed at the promotion of optimum community benefits and approved by a recognized standardizing body on the national, regional or international level for continuous application, with which compliance is not mandatory.

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WHAT IS A HARMONIZED STANDARD?

A standard developed under the mandate of the EU Commission by one of the recognized ESOs: CEN, CENELEC or ETSI

The reference of the standard and its related Directive is published in the Official Journal of the EU

Annex ZA of the standard details the Essential Requirement(s) of the directive that apply

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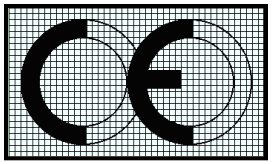
DIRECTIVE ≠ STANDARD

Directive

Legal obligation for manufacturers

Route for conformity assessment leading to self certification and CE marking



EN or national standard

Always voluntary

A means to demonstrate compliance to one or more clauses of the MDD (relevant clauses stipulated in the EN)

Note: The IVDD relies on CTS (common technical specifications) which are mandatory!

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TYPES OF STANDARDS

Horizontal standards address broad aspects, common to all medical devices

- Quality systems
- Risk management
- Labeling and symbols
- Clinical evaluation

Semi-horizontal standards address a set of requirements common to a group of devices

- Sterilization
- Biocompatibility

Vertical standards give detailed requirements for a specific device type

- EN 455 series on medical gloves for single use
- EN 794 series on lung ventilators

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TYPES OF STANDARDS

Manufacturing standards: Quality system, Packaging, cleanroom, …

Sterilisation standards: EtO, Gamma, Indicators, ….

Product Safety: Biocompatibility, DEHP levels for PVC, …

Environmental standards

Information standards (user interface, ...)

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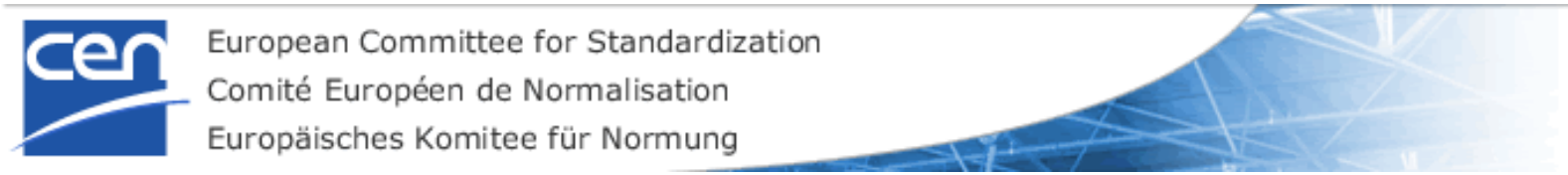
STANDARDS DEVELOPMENT IN EUROPE



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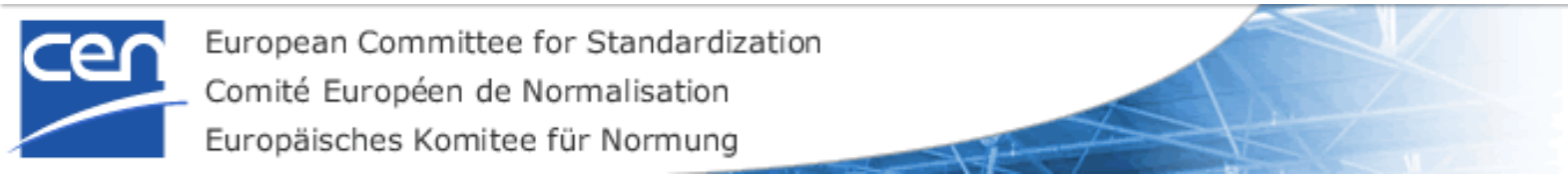
WHAT IS CEN?



Members: National Standards Bodies of 30+ European countries, i.e. BSI, AFNOR, DIN, …

Members: 6 Associates (organizations representing social and economic interests at European level)

Central Secretariat (Brussels)

Counterpart of ISO – Co-operation in place

Work groups organised by Members

Weighed voting: need 71% for approval

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WHAT IS ISO?

Members: National Standards Bodies of 156 countries , i.e. BSI, AFNOR, DIN, ANSI, …

Almost 3000 technical bodies in place (committees, subcommittees, working groups, ..)

Central Secretariat (Geneva)

38 Member bodies organise secretariat of committees

Produces about 1200 new documents (standards and guidelines) per year

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STANDARDS ACTIVITIES IN EUROPE

- 37 TCs / 200+ WGs working on developing standards for healthcare products
- Published standards are subject to 5 year revision process
- 500+New work items/year proposed by stakeholders via member standards organisations
- Mandated standards are quasi mandatory

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WORK PROCESS

Technical Committee initiates a work “new work item #…” on request of one or more Member States

A WG is assigned, made of experts representing national CEN members (get nominated through Unamec)

Also representatives from liaison members

Mirror groups organized at national level by NSB : In Belgium by Unamec for NBN

Work process and contents reviewed by the NSBs

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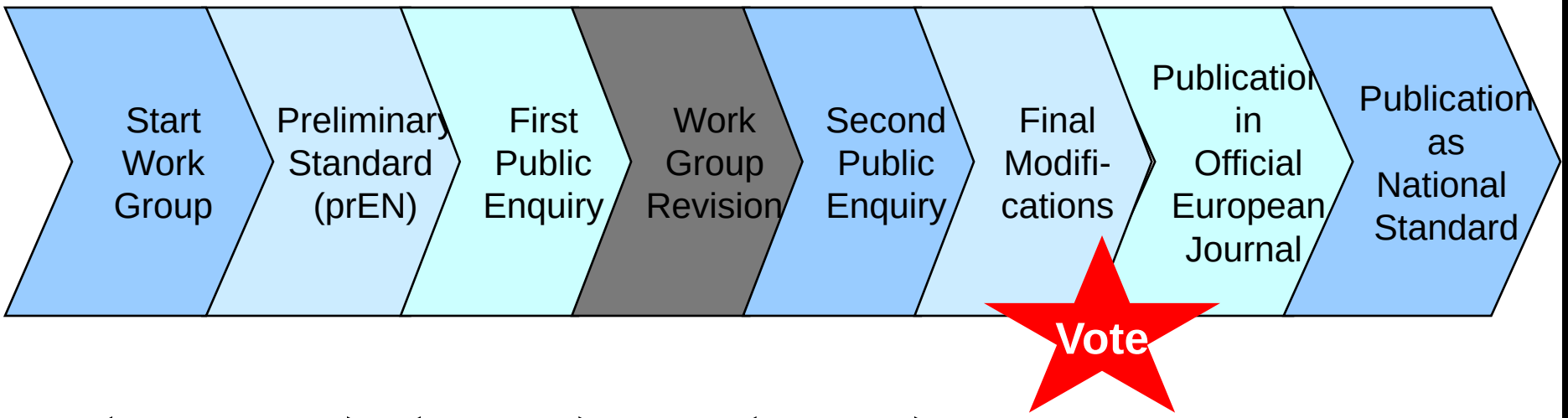
EN DEVELOPMENT PROCESS



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