

Role of Standards in the Assessment of Medical Devices

Klaus E. Stinshoff
European RA/QA Director
Digene Europe



Regulation of Medical Devices

challenging undertaking:

- devices with high **risk** potential
- wide spectrum of **technical/scientific concepts**
- material of **diverse origin and properties**
- high rate of **innovation**



New and Global Approach of the EU

- **essential requirements** = safety and efficiency
- **essential requirements** = broad and general formulation
- specific product requirements through **Harmonised Standards**
- consistency through **Quality Management Systems**

Medical Devices Directives

proof of compliance with essential requirements:

- what is **good enough**?
- what suffices in terms of **technical documentation**?

Harmonised Standards

for given **essential requirements** or processes

- the European Commission **mandates and finances** the development of certain standards by CEN/CENELEC/ETI
- decides about their **acceptability**
- publishes their reference in the **Official Journal of the European Communities**
- and therewith gives them the status of **Harmonised Standards**

Harmonised Standards in the CE Marking Process

- compliance = **assumption of conformity**
- key role in **technical documentation**
- certification by **conformity assessment bodies**
- audits by **regulatory authorities**
- **voluntary**

Characteristics of Recognized Standards







- not mandated but **selected** if corresponding to specific regulations
- national or international standards from **various sources**
- **evaluated** by regulatory authority
- published in the respective **official register, gazette or journal** (including target regulations and devices)

Recognized Standards in FDA Processes

- compliance with recognized standards: **indication, not proof** of compliance
- recognized standards to be **documented** in “certificate of conformance”
- compliance with standard **may replace detailed examination**
- FDA may still examine data/processes in detail



Table 10 - Interpretation of Labelling Symbols

<ul style="list-style-type: none"> x Only one product in the box x Do not use 2 products at a time x Not for use in February x Can be used single handed ✓“Do not Reuse” 	
<ul style="list-style-type: none"> x Mine's a half x For keyhole surgery x Cosmetic body shaping product x Short measures x Radical Compression hosiery ✓“Use By” 	
<ul style="list-style-type: none"> x More than one in a box x Up for auction x You'll like this product, but not a ✓“Batch Code” 	
<ul style="list-style-type: none"> x Staff Nurse only to use x Owned by senior nurse x Sado-Narcissus product x 'Supernatural' product ✓“Serial Number” 	<p>SN</p>
<ul style="list-style-type: none"> x As used in the House of Commons/Church x Manual prosthesis x Use this way up x Already incinerated ✓“Date of Manufacture” 	 <p>1998.06</p>
<ul style="list-style-type: none"> x Infertility device x Sterile field x Do not touch this product during use ✓“Sterile” 	
<ul style="list-style-type: none"> x Non-productive senior manager x End of product is sterile ✓“Sterilized using ethylene oxide” 	

Recognized / Harmonized Standards

are valued by

- regulators
- conformity assessment bodies
- industry

Global Standards Bodies

- should realize **structural requirements** for the development of recognized/harmonized standards
- should **support compliance** with these needs
- should be engaged in **negotiations with governments** and supranational institutions