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medicine
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Regulations in the EU

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Presentation

- Brief overview of the medical devices directives
- Basic elements of regulation
- In vitro-diagnostic medical devices directive
- Classification
- Standards and common technical specifications
- Conformity assessment procedures
- Meeting the essential requirements
- Traceability of values/Calibrator /control material



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Council Directives on the approximation of the laws of the Member States

- 90/385/EEC of 20 June 1990 relating to active implantable medical devices
- 93/42/EEC of 14 June 1993 concerning medical devices
- 98/79/EC of 27 October 1998 on in vitro diagnostic medical devices
- 2000/70 EC of 16 December 2000 on stable derivatives of human blood or human plasma as amended by 2001/104/EC



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Basic elements of regulation

- Mandatory Essential Requirements
- Use of voluntary harmonized standards *
- Variety of conformity assessment procedures related to various classes of risks
- Choice of conformity assessment procedures
- CE marking
- Vigilance
- Safeguard clauses
- Precautionary principle

* Common technical specifications



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In-vitro diagnostic medical devices- definition

'in vitro diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination,

intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body,

solely or principally for the purpose of providing information:

- concerning a physiological or pathological state, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures.



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In-vitro diagnostic medical devices definition - cont.

'....Specimen receptacles' are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.

Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination;



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Classification - by risk

High Risk in Annex II

- | | |
|--------|---|
| List A | Blood typing i.e. ABO systems
Blood born diseases i.e. HIV |
| List B | Specific tests i.e. HLA tissue groups |



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Classification -by risk cont.

Medium risk

Self test ie blood glucose , pregnancy

Low risk

Not annex II or self test ‘General IVDs’

Special rules for products for performance evaluation



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Standards and Common Technical Specifications

For Annex II List A and B

Performance evaluation and Re-evaluation

Batch release criteria

Reference methods

Reference materials



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Use of voluntary harmonized standards

- Technological flexibility and choice
- European standards can provide presumption of conformity
- European standardization has close links with international standardization



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Conformity assessment procedures

- Meet the essential requirements (Annex 1) +
- Graduated according to risk
- Intervention of a conformity assessment body for high and medium risk products
- Manufacturer's obligations



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Mandatory Essential Requirements Contained in Annex I of 98/79/EC

- Risk assessment
- Risk management
- Risk/benefit analysis
- Performance
- Specific requirements



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Annex 1

- Risk/benefit
- Suitable for the purpose defined by the manufacturer ref 'state of the art'
- Analytical sensitivity + specificity
- Diagnostic sensitivity + specificity
- Accuracy
- Repeatability
- Reproducibility



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Annex 1 cont

For Instruments

- Accurate measurement
- reference measurement procedures
- reference materials
- Legal units
- 80/181/EEC as last amended by 89/617/EEC



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Traceability of values

‘The traceability of values assigned to calibrators and/or control materials must be assured through available reference measurement procedures and/or available reference materials of a higher order.’

Annex 1 (3) 2nd para



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Calibrator /control material

‘For the purposes of this Directive, calibration and control materials refer to any substance, material or article intended by their manufacturer either to establish measurement relationships or to verify the performance characteristics of a device in conjunction with the intended use of that device.’

Article 1(3)



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CE Marking

- All in-vitro diagnostic medical devices ‘CE’
- When Notified Body is involved also their number ‘CE XXX’
- Transitional period until 7 December 2003



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Information

- http://europa.eu.int/comm/enterprise/medical_devices/index.htm
- <http://www.newapproach.org>
- <http://www.eotc.be>