



European Commission

Directive 98/79/EC on *in vitro* diagnostic medical devices in the context of genetic testing

EuroGentest Workshop on Genetic Testing and the In Vitro Diagnostic Directive

University of Leuven, Belgium, 24 April 2007

John Brennan  
DG Enterprise and Industry, Unit F3

[john.brennan@ec.europa.eu](mailto:john.brennan@ec.europa.eu)



European Commission

## Medical Devices in the EU

Three main areas of involvement:

- Access to a common internal market
- Trade facilitation and regulatory convergence
- Competitiveness of industry



European Commission

## Article 95 of the Treaty (1)

...to “adopt measures for the approximation of the provisions laid down by law, regulation of administrative action in Member States which have as their objective the establishment and functioning of the internal market”...



European Commission

## Article 95 of the Treaty (2)

...taking as a base “a high level of protection ... based of scientific facts”, i.e. “danger for human health”...

...

...”the harmonisation ... include a safeguard clause”.



European Commission

## Article 152 of the Treaty

“Public health”

...”a high level of human health protection shall be ensured in the definition and implementation of ALL community policies and activities”...



European Commission

## EU Directives on Medical Devices

### Concern only:

- Placing on the market
- or
- Putting into service



European Commission

## EU Directives on Medical Devices

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



European Commission

## Other relevant documents

- Commission Decision 2002/364/EC on common technical specifications for in-vitro diagnostic medical devices (Annex II, List A IVDs performance and release testing)
- Guidelines (MedDevs) adopted by stakeholders in the framework of the Medical Devices Experts Group
- European Standards
- Guidance documents developed by Notified Bodies.



European Commission

## Medical Devices

### Definition-

Medical device means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings, for the purpose of....



European Commission

## Medical devices definition

Diagnosis, prevention, monitoring, treatment or alleviation of disease; alleviation or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; control of conception.....



European Commission

## Medical device definition

- and which does not achieve its principal intended action in or on the human body by

Pharmacological

Immunological

Metabolic

(but which may be assisted in its function by such means)



European Commission

## ***in vitro* diagnostic medical device 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: ...



European Commission

## ***in vitro* diagnostic medical device definition**

- 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.



European Commission

## *in vitro* diagnostic medical device definition

- (8) Whereas instruments, apparatus, appliances, materials or other articles, including software, which are intended to be used for research purposes, **without any medical objective**, are not regarded as devices for performance evaluation;



European Commission

## ***in vitro* diagnostic medical device definition**

- (9) Whereas, although internationally certified reference materials and materials used for external quality assessment schemes are not covered by this Directive, calibrators and control materials needed by the user to establish or verify performances of devices are *in vitro* diagnostic medical devices;



European Commission

## ***in vitro* diagnostic medical device definition**

**Specimen receptacles** are considered to be *in vitro* diagnostic medical devices. ‘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;



**MEDDEV 2.14/1 rev 1**

**8. Control Materials**

Some EQA organisations distribute materials for internal control, national calibration materials, etc. These materials are IVD's and must bear the CE label.

	<b>CE Label</b>	<b>Remarks</b>
Calibrators/Controls included in the kit	Part of the kit	Calibrators and controls with assigned values must be traceable
Standing alone calibrators and internal quality control (IQC) materials (assigned or not assigned) Even if these materials are also used as EQA Materials	CE label	Calibrators and controls with assigned values must be traceable
Specific EQA materials	No CE label	Reference Recital (9) of 98/79/EC
Reference material of higher order	No CE label	Metrological traceability required



European Commission

## *in house concept - Article 1 (5)*

This Directive shall not apply to devices manufactured and used only within the same health institution and on the premises of their manufacture or used on the premises in the immediate vicinity without having been transferred to another legal entity. This does not affect the right of Member State to subject such activities to appropriate protection requirements.



European Commission

## Basic elements of regulation

- Mandatory Essential Requirements
- Flexibility on technology used to meet ERs
- CTS – Common Technical Specifications (performance and release testing)
- Presumption of conformity by using European (“harmonized”) Standards
- Variety of conformity assessment procedures related to various classes of risks; Annex II List A, Annex II List B, performance evaluation, self test
- CE marking
- Market surveillance and Vigilance
- Intervention mechanisms by public authorities



European Commission

## Annex II, List A

- Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups: ABO system, rhesus (C, c, D, E, e) anti-Kell,
- reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of HIV infection (HIV 1 and 2), HTLV I and II, and hepatitis B, C and D.



European Commission

## Annex II, List B

- Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups: anti-Duffy and anti-Kidd,
- reagents and reagent products, including related calibrators and control materials, for determining irregular anti-erythrocytic antibodies,
- reagents and reagent products, including related calibrators and control materials, for the detection and quantification in human samples of the following congenital infections: rubella, toxoplasmosis,
- reagents and reagent products, including related calibrators and control materials, for diagnosing the following hereditary disease: phenylketonuria,



European Commission

## Annex II, List B

- reagents and reagent products, including related calibrators and control materials, for determining the following human infections: cytomegalovirus, chlamydia,
- reagents and reagent products, including related calibrators and control materials, for determining the following HLA tissue groups: DR, A, B,
- reagents and reagent products, including related calibrators and control materials, for determining the following tumoral marker: PSA,
- reagents and reagent products, including related calibrators, control materials and software, designed specifically for evaluating the risk of trisomy 21,
- the following device for self-diagnosis, including its related calibrators and control materials: device for the measurement of blood sugar.



European Commission

## Actors involved in implementation

- European Commission
- National Authorities
- Notified Bodies
- European Standards Bodies
- Industry
- Advisory bodies (Scientific Committee)



European Commission

## CE Marking

The CE marking symbolizes the conformity of the product with the applicable Community requirements.

The CE marking affixed to products is a declaration by the person responsible that:

- the product conforms to all applicable Community provisions, and
- the appropriate conformity assessment procedures have been completed



European Commission

## IVD Directive and Genetic Testing

- Contains all essential requirements
- Covers the product, not the broader aspects of testing (e.g. who should test or how testing should be regulated)
- Only applicable to products placed on the market and put into service



European Commission

The End

Thank You

John Brennan  
DG Enterprise and Industry, Unit F3

[john.brennan@ec.europa.eu](mailto:john.brennan@ec.europa.eu)

0032 2 298 50 24