dgcis direction générale de la compétitivité de l'industrie et des services

REGULATIONS HARMONISED AT EUROPEAN LEVEL

IN VITRO DIAGNOSTIC MEDICAL DEVICES

SCOPE

The following definitions apply:

➔ '*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 mainly 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

Specimen receptacles are considered as *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 the said products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination.

➔ 'Accessory' means an article that, although it is not an *in vitro* diagnostic medical device, is intended specifically by its manufacturer to be used together with a device to enable the said device to be used in accordance with its intended purpose.

For the purposes of this definition, invasive sampling devices or those that are directly applied to the human body for the purpose of obtaining a specimen within the meaning of Directive 93/42/EEC are not considered as accessories to *in vitro* diagnostic medical devices.

REGULATIONS

➢ EC LEGISLATION

- **Directive 98/79/EC** of 27 October 1998 on *in vitro* diagnostic medical devices

➢ FRENCH LEGISLATION

- **Decree No 2004-108** of 4 February 2004 on *in vitro* diagnostic medical devices and amending the Public Health Code (second part: Decrees adopted after consultation with the *Conseil d'Etat* (French Supreme Administrative Court))
- **Decree No 2011-971** of 16 August 2011 on reselling second-hand *in vitro* diagnostic medical devices
- **Public Health Code – Legislative part – Fifth part – Book II – Articles L.5211-1 et seq.**
- **Public Health Code – Regulatory part – Fifth part – Book II – Articles R.5211-1 et seq.**

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HARMONISED STANDARDS

■ List of harmonised standards on the European Commission's website
http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/iv-diagnostic-medical-devices/index_en.htm

CONTACTS

➢ AUTHORITY RESPONSIBLE FOR REGULATIONS

- *Ministère des affaires sociales et de la santé* (Ministry for Social Affairs and Health) :
  - Direction Générale de la Santé (DGS) – Bureau des dispositifs médicaux et autres produits de santé PP3 – stephan.ludot@sante.gouv.fr

➢ MARKET SURVEILLANCE AUTHORITIES

- Ministry for Social Affairs and Health :
  - ANSM (formerly AFSSAPS) – Direction de l'évaluation des dispositifs médicaux (DEDIM) dedim.dm@ansm.sante.fr – Telephone: +33 1 55 87 37 45

Applications for the classification of medical devices are filed with the ANSM – Direction de l'évaluation des dispositifs médicaux (DEDIM) – Département surveillance du marché – Unité des affaires réglementaires – dedim.dm@ansm.sante.fr

- *Ministère de l'économie et des finances* (Ministry for the Economy and Finance) :
  - DGCCRF – Bureau des produits et prestations de santé 5B bureau-5b@dgccrf.finances.gouv.fr
  - DGDDI (Customs) – Bureau D2 – dg-d2@douane.finances.gouv.fr

➢ NOTIFIED BODY

- Laboratoire national d'essais / G-MED
  1, rue Gaston Boissier – 75724 PARIS Cedex 15 – France
  Telephone: +33 1 40 43 37 00 – http://www.gmed.fr/

The LNE / G-MED is the only French notified body for European Directives on medical devices

➢ BUSINESS FEDERATIONS

- Syndicat de l'Industrie des Dispositifs de Soins Médicaux (APPAMED)
  37-39, rue de Neuilly – 92582 Clichy Cedex
  Telephone: +33 1 47 56 30 05 – Fax: +33 1 47 37 94 54 – http://www.appamed.org/
- **Union Nationale des Prestataires de Dispositifs Médicaux** (UNPDM)
  13-15, rue de Calais – 75009 Paris
  Telephone: +33 1 42 71 11 77 – Fax: +33 1 42 71 22 54
- Syndicat National de l'Industrie des technologies Médicales (SNITEM)
  Business address: 39 rue Louis Blanc – 92400 Courbevoie
  Postal address: 92038 Paris-La-Défense Cedex
  Telephone: +33 1 47 17 63 88 – Fax: +33 1 47 17 63 89 – http://www.snitem.fr/
- Association pour la Promotion de l'Innovation des Dispositifs Médicaux (A.P.I.DI.M.)
  http://apidim.org/index.html