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REGULATIONS HARMONISED AT EUROPEAN LEVEL

MEDICAL DEVICES

SCOPE

The following definitions apply:

➔ 'Medical device' means any instrument apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or handicap
- Investigation, replacement or modification of the anatomy or of a physiological process
- Control of conception and whose main action is through the metabolism, but whose function may be assisted by the said means

➔ 'Accessory' means an article that, although it is not a device, is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.

REGULATIONS

➢ EC LEGISLATION

■ **Directive 93/42/EEC** of 14 June 1993 concerning medical devices

➢ FRENCH LEGISLATION

■ **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*.**

■ **Decree No 2002-1221 of 30 September 2002 on categories of medical devices subject to communication when commissioned and amending Book V bis of the Public Health Code**

■ **Decree no 2010-270 of 15 March 2010 on the clinical assessment of medical devices and communication of ID data to the** National Agency for the Safety of Medicines and Health Products (ANSM)

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/medical-devices/index_en.htm

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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