

REGULATIONS HARMONISED AT EUROPEAN LEVEL

ACTIVE IMPLANTABLE MEDICAL DEVICES

SCOPE

The following definitions apply:

- 'Active medical device' means any medical device that, for its operations, relies on a source of electrical energy, or any source of power other than a source directly generated by the human body or gravity.
- 'Active implantable medical device' means any active medical device that is intended to be - totally or partially – introduced into the human body either by a surgical or a medical method, or introduced by a medical intervention into a natural orifice, and that is intended to remain after the procedure.

REGULATIONS

➤ **EU LEGISLATION**

- [Directive 90/385/EEC](#) of 20 June 1990 relating to active implantable 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.](#)

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/implantable-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.dsm@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.D.I.M.)

<http://apidim.org/index.html>