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"Regulations of medical device's instructions, labels and packaging marks"

(State Food and Drug Administration Ordinance No. 10)

2006-02-15 [Translator: February 15, 2006]

"Regulations of medical device's instructions, labels and packaging marks" has been approved on June 18, 2004 by the Works Council of the State Food and Drug Administration, and is hereby announced. This Regulations comes into force from the date of publication.

Secretary: Zheng Xiaoyu

July 8, 2004

Regulations of medical device's instructions, labels and packaging marks

Article 1 In order to regulate medical device's instructions, labels and packaging marks; to ensure the usage safety of medical device; and in accordance with "Supervisions and Regulations of medical device", this Regulations is formulated.

Article 2 All medical devices which are sold and used in the territory of the People's Republic of China shall attach instructions, labels and packaging marks, according to this Regulations' requirements. According to the provisions of the State Food and Drug Administration, easy-to-use products may omit 1 or 2 items of 3 items - instructions, labels and packaging marks, according to the provisions.

Article 3 Medical device's users shall use the medical device in accordance with the instructions.

Article 4 Medical device's instructions refer to those documents which are provided by the manufacturer and attached to the product; include product safety, effective and basic information; and are used for guidance for proper installation, commissioning, operation, use, maintenance and care.

Medical device's labels refer to those text, graphics and symbols attached onto the medical device or packaging, and used for identifying the product's characteristics.

Medical device's packaging marks refer to the text, graphics and symbols which are marked on the package and reflecting the main technical characteristics of the medical device.

Article 5 Contents of medical device's instructions, labels and packaging marks shall be true, complete, accurate and scientific; and be consistent with the product characteristics.
Contents of medical device's labels and packaging marks shall be consistent with the contents of the relevant instructions.

Article 6 The text of medical device's instructions, labels and packaging marks must use Chinese; other languages may be added. Use of Chinese shall comply with the national common specifications of the language.

The text, symbols, graphics, tables, figures, photographs and pictures of medical device's instructions, labels and packaging marks shall be accurate, clear and standardized.

Article 7 Medical device's instructions shall meet the relevant requirements of national standards or industry standards, generally it shall include the following contents:
(1) Product name, model and type;

(2) Manufacturer's company name, registered address, production address, contact information and the organization of after-sale-service;

(3) Certificate number of "Medical device's manufacturing enterprise permit license" (except for the class 1 medical device), registration certificate number of medical device;

(4) Product standard number;

(5) Product performance, the main structure and applicable scope;

(6) Contraindications, precautions and other contents requiring warning or caution;

(7) Contents' explanation of the graphics, symbols and abbreviations etc. which are used by the medical device's labels;

(8) Installation and instructions or icons;

(9) Product maintenance and care methods; special storage conditions and methods;

(10) For product with time-limited use, it shall indicate the expiry date;

(11) Other contents specified by the product standards to be indicated in instructions.

Article 8 Medical device's labels and packaging marks shall generally include following contents:

(1) Product name, model and type;

(2) Manufacturer's company name, registered address, production address and contact information;

(3) Registration certificate number of the medical device;

(4) Product standard number;

(5) Production date or batch (serial) number;

(6) Power connection's conditions, the input power;

(7) For product with time-limited use, it shall indicate the expiry date;

(8) Based on product characteristics, it shall indicate graphics, symbols and other related contents.

Article 9 Medical device's instructions, labels and packaging marks must not have following contents:

(1) Contain such expressions "the best effect", "guaranteed cure", "sure-cure", " complete

instructions mainly include:

(1) Possible side effects of using the product;

(2) When accident occurs during the proper using of the product, the protective measures to the operators and users; and the emergency and corrective measures which shall be adopted;

(3) One-time-use product shall be marked with "one time use" words or symbols;

(4) Sterilized product shall indicate sterilization; marked with "sterilized" words or symbols; and indicate the treatment method after the sterile packaging is damaged;

(5) If the product requires disinfection or sterilization before it is used, disinfection or sterilization methods shall be explained;

(6) When the product needs to be installed or coordinately operated with other products, it shall indicate the requirements for coordination use;

(7) In the course of usage, the possible mutual interference and potential dangers with other products;

(8) If the product needs to be treated after used, it shall indicate the appropriate treatment method;

(9) According to the product characteristics, other matters which shall prompt the operator and user to pay attention to.

Article 14 Contents relating to the installation in medical device's instructions shall be able to ensure the operator and user to properly install and use; it shall include:

(1) Product installation instructions and technical drawings, wiring diagrams;

(2) The environmental conditions required for proper product installation; and the technical information to identify whether it is properly installed;

(3) Other special installation requirements.

Article 15 When medical device's Instructions are applied for registration by the manufacturer, it shall be submitted to (Food) Drug Administration for review in accordance with the "Registration management method of medical device"; the submitted contents of the medical device's Instructions shall be consistent with other materials of registration and

etc.] within 20 working days; the manufacturer shall handle the requirements in accordance with the notice.

Article 20 The manufacturer who violates this Regulations with one of the following behaviors shall be given a warning by the county-level-or-above (Food) Drug Administration; shall be ordered to correct in limited time; and shall be recorded into the corporate governance files of the manufacturer:

(1) Unauthorizedly change the contents of instructions which have been registered, audited and filed;

(2) The labels and packaging marks of marketing products are contrary to the contents of instructions which have been registered, audited and filed; or are in violation of other requirements of this Regulations;

(3) Medical device's product name or brand name is in violation of this Regulations;

(4) Marketing product fails to attach the instructions, labels and packaging marks per requirements of provisions; easy-to-use product may be excepted if there is applicable provision by State Food and Drug Administration [Translator: Please refer Article 2].

Article 21 If the medical device's manufacturer unauthorizedly increases the product scope or product indications in the instructions of the medical device, county-level-or-above (Food) Drug Administration shall punish the manufacturer in accordance with the 35th provision of "Supervision and regulation of medical device" – the situation of without obtaining a registration certificate of medical device.

Article 22 The State Food and Drug Administration shall be responsible to interpret this Regulations.

Article 23 This Regulations shall take into effect since the announcement of the date. The "Regulations of medial device's Instructions" released by State Food and Drug Administration on January 4, 2002 shall be simultaneously abolished.

[Original Chinese Text]

《医疗器械说明书、标签和包装标识管理规定》（国家食品药品监督管理局令第 10 号）

2006-02-15

《医疗器械说明书、标签和包装标识管理规定》于 2004 年 6 月 18 日经国家食品药品监督管理局局务会审议通过，现予公布。本规定自公布之日起施行。

局长：郑筱萸

二〇〇四年七月八日

医疗器械说明书、标签和包装标识管理规定

第一条　为规范医疗器械说明书、标签和包装标识，保证医疗器械使用的安全，根据《医疗器械监督管理条例》，制定本规定。

第二条　凡在中华人民共和国境内销售、使用的医疗器械应当按照本规定要求附有说明书、标签和包装标识。简单易用的产品，按照国家食品药品监督管理局的规定，可以省略说明书、标签和包装标识三项中的某一项或者某两项的，依照其规定。

第三条　医疗器械的使用者应当按照医疗器械说明书使用医疗器械。

第四条　医疗器械说明书是指由生产企业制作并随产品提供给用户的，能够涵盖该产品安全有效基本信息并用以指导正确安装、调试、操作、使用、维护、保养的技术文件。

医疗器械标签是指在医疗器械或者包装上附有的，用于识别产品特征的文字说明及图形、符号。

医疗器械包装标识是指在包装上标有的反映医疗器械主要技术特征的文字说明及图形、符号。

第五条　医疗器械说明书、标签和包装标识的内容应当真实、完整、准确、科学，并与产品特性相一致。

医疗器械标签、包装标识的内容应当与说明书有关内容相符合。

第六条　医疗器械说明书、标签和包装标识文字内容必须使用中文，可以附加其他文种。中文的使用应当符合国家通用的语言文字规范。

医疗器械说明书、标签和包装标识的文字、符号、图形、表格、数字、照片、图片等应当准确、清晰、规

（一）含有“疗效最佳”、“保证治愈”、“包治”、“根治”、“即刻见效”、“完全无毒副作用”等表示功效的断言或者保证的；

（二）含有“最高技术”、“最科学”、“最先进”、“最佳”等绝对化语言和表示的；

（三）说明治愈率或者有效率的；

（四）与其他企业产品的功效和安全性相比较的；

（五）含有“保险公司保险”、“无效退款”等承诺性语言的；

（六）利用任何单位或者个人的名义、形象作证明或者推荐的；

（七）含有使人感到已经患某种疾病，或者使人误解不使用该医疗器械会患某种疾病或加重病情的表述的；

（八）法律、法规规定禁止的其他内容。

第十条　医疗器械的产品名称应当符合国家相应的标准和规定。

第十一条　医疗器械的产品名称应当清晰地标明在说明书、标签和包装标识的显著位置，并与医疗器械注册证书中的产品名称一致。

第十二条　医疗器械有商品名称的，可以在说明书、标签和包装标识中同时标注商品名称，但是应当与医疗器械注册证书中标注的商品名称一致。同时标注产品名称与商品名称时，应当分行，不得连写，并且医疗器械商品名称的文字不得大于产品名称文字的两倍。

医疗器械商品名称中不得使用夸大、断言产品功效的绝对化用语，不得违反其他法律、法规的规定。

第十三条　医疗器械说明书中有关注意事项、警示以及提示性内容主要包括：

（一）产品使用可能带来的副作用；

（二）产品在正确使用过程中出现意外时，对操作者、使用者的保护措施以及应当采取的应急和纠正措施；

（三）一次性使用产品应当注明“一次性使用”字样或者符号；

（四）已灭菌产品应当注明灭菌方式，注明“已灭菌”字样或者标记，并注明灭菌包装损坏后的处理方法；

（五）使用前需要消毒或者灭菌的应当说明消毒或者灭菌的方法；

（六）产品需要同其他产品一起安装或者协同操作时，应当注明配合使用的要求；

（七）在使用过程中，与其他产品可能产生的相互干扰及其可能出现的危险性；

（八）产品使用后需要处理的，应当注明相应的处理方法；

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