Regulation on Instructions for Use, Labels and Packaging Logos of Medical Devices

Article I
The Regulation is enacted in accordance with the "Medical Devices Administration & Management Rules" to standardize the Instructions for Use, labels and packaging logos of Medical Devices and ensure the safety of Medical Device applications.

Article II
Any Medical Device for sale and use in People's Republic of China shall have Instructions for Use, label and packaging logo in accordance with the requirements of the Regulation. Two or three items of the Instructions for Uses, labels and packaging logos can be combined.

Article III
The Instructions for Use of Medical Devices refer to technical documentations made by the applicant and provided to users that can include the efficient basic information on product safety and can be used for guidance for proper installation, test, operation, use, service, and maintenance.
The labels of Medical Devices refer to the textual descriptions, graphics, and symbols that are attached to the body or packaging of Medical Device products and used to identify the features of products.
The packaging logos of Medical Devices refer to the textual descriptions and graphics that are indicated on (or inside) the packaging to reflect the key technical features of Medical Devices.

Article IV
Users of Medical Devices should use Medical Devices according to the Instructions for Use of Medical Devices.

Article V
The content of Instructions for Use, labels and packaging logos of Medical Devices should be true, complete, accurate, scientific, and consistent with the features of products. The content of labels and packaging logos of Medical Devices should be consistent with the related content in the Instructions for Use.

Article VI
The disease names, professional terms, and description of diagnosis & treatment processes and results of Instructions for Use, labels and packaging logos of Medical Devices should use special vocabulary unified issued or promulgated by the nation, and the units of measurements should be in line with the regulation of national standards.

Article VII

The content of Instructions for Use, labels and packaging logos of Medical Devices can be expressed in the form of symbols, and the symbols or identification colors used should meet the regulation of relevant national standards. If there is no related standard, the symbols and colors should be described in the attached Instructions for Use of the Medical Device.

Article VIII

The product names of Medical Devices shall comply with relevant national standards and the principles of Medical Device nomenclature developed by the National Food and Drug Administration. The product name of a Medical Device should be clearly marked on prominent locations of the Instruction for Use, label and packaging logo and be consistent with the product name in the Medical Device Registration Certificate / Record Information Table.

Article IX

The Instruction for Use, label and packaging logo of a Medical Device shall not have the following contents:

i. Contents having declaration or guarantee for functions and effects such as "best curative effect", "guarantee to cure", "guarantee a cure", "effect a cure ", "effective immediately", "completely non-toxic and no side effect" and so on;
ii. Contents having absolute words and representations such as "the highest technology", "most scientific", "most advanced", "best" and so on;
iii. Contents expressing its cure rate or efficiency;
iv. Contents having comparison of efficacy and safety with products from other enterprises;
v. Contents having words that guarantee such as "insured by an insurance company" and "refund if no effect" and so on;
vi. Contents using the name of any organization or individual to prove or recommend;
vii. Contents having misleading statement that makes people feel that he or she has been suffering from a disease, or misleads one to believe that he or she will get ill or aggravate his or her illness without using the Medical Device;
viii. Contents prohibited by any law or regulations.

Article X

Incomplete description as a result of limited packaging logo or label size of a Medical Device shall expressly indicate "see Instruction for Use for more details" on the label and the packaging logo.

Article XI

The textual content of Instruction for Use, label and packaging logo of a Medical Device shall use Chinese, and other language(s) can be attached. The use of Chinese shall comply with the national general specifications for Chinese language and words.

The words, symbols, tables, figures, graphs, and so on in the Instruction for Use, label and packaging logo of a Medical Device shall be accurate, clear, and standard.

Article XII

The Instruction for Use of a medical device should contain important scientific data, conclusions and information related to the safety and effectiveness of the medical device to be used for guiding the use of the device safely and properly.

Article XIII

The Instruction for Use of a Medical Device should meet relevant requirements of national standards or industry standards and should generally include the following contents:

i. Product name, model, and size;
ii. The name of the applicant, registered address, manufacturing address, contact information, and after-sales service organization;
iii. The registration number or record number of the Medical Device;
iv. The preparation or revision date and version information of the Instructions for Use;
v. The structures and composition;
vi. The performance indicators;
vii. A brief description of the operational principle or functional mechanism;
viii. The intended use;
ix. Contraindication and forbidden to use information;
x. Description of installation, test, and usage;
xi. Precautions and warnings;
xii. Interpretation of contents such as graphics, symbols, abbreviations and so on used in the Medical Device;
xiii. The maintenance and repair methods for the product as well as special storage, transportation conditions, and methods;
xiv. Regulations for cleaning, disinfection and sterilization;
xv. The effective period shall be indicated for any product with limited period of use;
xvi. Other contents that shall be indicated in the Instruction for Use according to the regulations of product standards.

Article XIV

The Instruction for Use should provide the information of contraindications of the product. The information of contraindications should be right after the intended use section in the Instructions for Use, and "no known contraindications" should be clearly indicated if there is no contraindication.

Article XV

Contents related to precautions, warnings, and reminders in the Instruction for Use of a Medical Device mainly include:

i. Users of the product;
ii. The potential safety hazards and use restrictions;
iii. The protective measures for operators and users when unexpected condition occurs during the correct use of the product, as well as the emergency and corrective measures that should be taken;
iv. The necessary tools for control, monitoring and evaluation as well as special groups;
v. Any disposable product should be marked "Disposable" by word or symbol; any sterilized product should indicate the sterilization method, "Sterilized" word or mark, as well as the treatment method when the sterilized packaging is damaged; and any product that requires disinfection or sterilization before use should indicate the method used for disinfection or sterilization;
vi. Any product that needs to be installed in conjunction or used in combination with other Medical products should indicate the requirements, usage and precautions of products used in combination;
vii. Mutual interference with other products that may happen during the use process and danger that may probably appear;
viii. Issues that should pay attention to when discarding Device to avoid any special or unusual risk, and any product that requires treatment after use should indicate the relevant treatment methods;
ix. Other issues that should prompt the operators and users to pay attention to based on the characteristics of the product.

Article XVI

Possible side effects that may come with the use of products, or ingredients or accessories that the product ingredients contain and may have side effects, should be described in the Instructions for Use.

Article XVII

For products that may be reused, appropriate processing procedure including methods for cleaning, disinfection, packaging and sterilization as well as the limits on the number of reuses should be clearly indicated in the Instructions for Use

Article XVIII

Part List shall be attached to the Instructions for Use, and specifications and models of parts, accessories, consumables, replacement cycles of parts and replacement method should be described.

Article XIX

The label of a Medical Device should include the basic information of the applicant of the Medical Device, the basic information of the medical product, and the basic information such as necessary warnings and precautions, including processing method prior to the use of the device such as sterilization, assembling, calibration, and so on..

Article XX

The label of a Medical Device should generally include the following:

i. Product name, model, and size;
ii. The name of the applicant, registered address, manufacturing address, contact information, and contact information;
iii. The registration number or record number of the Medical Device;
iv. The manufacturing date of the product or batch number (series number), and date of sterilization;
v. Power connection conditions and the input power;
vi. The effective period shall be indicated for any product with limited period of use; any sterilized product should indicate the date of sterilization;
vii. Graphics, symbols and other related content that should be labeled in accordance with the product’s features;
viii. Necessary warnings and precautions;
ix. Special storage and operation conditions or instructions.

Article XXI

The Valid Period in the label of a Medical Device should be labeled in the order of year, month, and date, the year should be expressed with a four-digit number, and month and date with two digit numbers. The specific label format is "valid until XXXX (year) XX (month)" or "valid until XXXX (year) XX (month) XX (date)"; it can also be expressed using numbers and other symbols as "valid until XXXX.XX." or "valid until XXXX / XX / XX "and the like.

If the Valid Period is labeled to date, the date should be one day prior to the corresponding date of the starting date; if labeled to month, the month should be one month prior to the corresponding month of the starting month.

Article XXII

The label of any Medical Device for implanting or long-term indwelling in the body should contain a unique traceable code. The unique code should be consistent with the relevant regulations of the State Food and Drug Administration.

Article XXIII

The label of any Medical Device having destructive or negative impact on the environment in use should indicate the materials having impact on the environment and their effects on the environment (for example, the use of Freon destructs the ozone layer). The treatment of after-use waste should be expressed.

Article XXIV
The label of any Medical Device having radioactivity or radiation should include warning sign or warning notes in Chinese, indicating the nature, type, intensity and distribution of the radiation and the operation precautions.

Article XXV
The label of packaging of any Medical Device should have, in addition to the content of Article XX, storage conditions and transport considerations, special storage conditions, and necessary treatment methods after using the product.

Article XXVI
The minimum packages of Medical Devices for sale should have Instructions for Use inside.

Article XXVII
The label of packaging of any Medical Device should contain the label of opening the sterile packaging to prevent secondary use; if repeated sterilization is allowed, the methods and conditions of repeated sterilization should be indicated.

Article XXVIII
The Instructions for Use of a Medical Device should be submitted to the Food and Drug Administration for examination or put on record by the applicant when applying for registration or filing of putting on record of the Medical Device in accordance with the "Medical Device Registration (Record) Regulation", and the Instructions for Use filed should be consistent with other registrations or filed information.

Article XXIX
The applicant should not change the contents of the Instructions for Use without authorization. When change of the contents of registration reviewed Instructions for Use of a Medical Device without involving technical change of the product, the applicant shall submit related documents such as comparison description of the changes of Instructions for Use, and report to the original registration and examination department of the Medical Device registrations by written notification.

Article XXX
The change of the Instructions for Use shall go into effect and be put into record if the original registration and examination department has not sent out written notice of disagreement within 20 working days after receiving the applicant’s written notification of changing the Instructions for Use; if the original registration and examination department has sent out a written notice within 20 working days, the applicant shall work in accordance with the requirements of the notice.

Article XXXI

The change of the Instructions for Use by the applicant, if not involving the conditions required to file the change record information according to the "Medical Device Registration (Record) Regulation", shall be recorded in accordance with the relevant requirements of the quality management system; and if involving the conditions required to file the change record information, the change record information shall be filed.

Article XXXII

If the change of the Instructions for Use involves conditions required to file registration change according to the requirement of the "Medical Device Registration (Record) Regulation", the change shall not be handled as the change of the Instructions for Use.

Article XXXIII

Violation of the Regulation and having any of the following shall be given a warning by the Food and Drug Administration of county or higher level and shall be mandated to modify during the limited period:

i. Unauthorized change of the contents of the registration reviewed Instructions for Use;
ii. The label and packaging logo of the product on sale violate the contents of the registration reviewed Instructions for Use or other requirements of the Regulation;
iii. The product on sale does not attach Instructions for Use, label and packaging logo as required by the Regulation.

Article XXXIV

If the applicant for registration of the Medical Device adds the application scope, indications, or intended use in the Instructions for Use of the Medical Device without authorization, the Food and Drug Administration department shall punish as having not obtained the certificate of registration of Medical Devices in accordance with the conditions in the "Medical Devices Administration & Management Rules".

Article XXXV

The State Food and Drug Administration shall be responsible for the interpretation of the Regulation.

Article XXXVI

The Regulation shall be implemented since × (month) × (date), 2014.