Norma Oficial Mexicana NOM-137-SSA1-2008: Labeling of medical devices
United Mexican States - Ministry of Health
NOM-137-SSA1-2008, LABELING OF MEDICAL DEVICES

WHEREAS

That on July 26, 2005, in compliance with the provisions of Article 46 Section I of the Act Federal Metrology and Standardization, the Federal Commission for Protection Against Health Risks submitted to the National Advisory Committee on Health Regulation and Development, the draft of this Official Mexican Standard.

That dated April 25, 2008, in compliance with the agreement of the Committee and the provisions of Article 47 section I of the Federal Law on Metrology and Standardization, was published in the Official Journal of the Federation this draft of the Mexican Official Standard, to the effect that within the following sixty calendar days following such publication, interested parties shall submit their comments to the National Advisory Committee on Health Regulation and Development.

On that earlier date, the responses to comments received by the said Committee were published in the Official Journal of the Federation, under the terms of Article 47 section III of the Federal Law on Metrology and Standardization.

That in view of the previous considerations, with the approval of the National Advisory Committee on Standards and Sanitary Regulations, the following was issued:

12 (Third Section) Official Journal Friday December 12, 2008

PREFACE

The following institutions participated in the preparation of this Official Mexican Standard:
SECRETARY OF HEALTH.
LEGAL AFFAIRS DIRECTORATE.
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1. Objective and scope

1.1 Objective.
This Official Mexican Standard establishes minimum requirements that serve to communicate the information to users, which should contain the labeling of medical devices (medical equipment, prosthetics, orthotics, functional aids, diagnostic agents, dental supplies, surgical materials, materials for healing and hygienic products) of domestic or foreign origin, which are marketed or intended for users in the country.

1.2 Scope.
This Mexican Official Standard is mandatory for all establishments engaged in manufacturing, packaging, importing and distributing of medical devices.

2. References.
For the correct application of this Mexican Official Standard, you should check the following standards:

2.3 Pharmacopoeia of the United Mexican States and its Supplements.

3. Definitions
For purposes of this Mexican Official Standard the following are defined as:

3.1 Conditioning, the operations that a bulk product should go through to reach its presentation as a finished product.
3.2 Warning, the written guideline or legend with instructions to prevent the user from taking on some risk in the process of using a medical device.
3.3 Diagnostic Agent, all substances including antigens, antibodies, calibrators, verifiers and controls, reagents, reagent equipment, culture and contrast media and other similar substances that can be used as an auxiliary of other clinical or paraclinical procedures.
3.4 Functional Aids, substances without pharmacological properties that help improve body function.
3.5 Storage conditions, those conditions that result in the development of stability tests for medical devices.
3.6 Back label, the label that contains the additional health and marketing information, or the total mandatory minimum information required, when the label of origin partly or wholly fails to meet this requirement.
3.7 Distinctive name, the trademark name assigned to the laboratory or manufacturer of the medical device in order to distinguish them from other similar devices.

3.8 Generic name, the name that describes a medical device or group of medical devices having common characteristics, accepted by the health authority.

3.9 Medical device, a substance, mixture of substances, material, device or instrument (including computer program necessary for proper use or application), used alone or in combination with the diagnosis equipment, monitoring or prevention of disease in humans or aids in the treatment of the same and disability, such as are used in the replacement, correction, restoration or modification of the anatomy or human physiological processes. Medical devices include the following product categories: medical equipment, prosthetics, orthotics, functional aids, diagnostic agents, dental supplies, surgical and healing materials and hygiene products.

3.10 Bulk medical device, the medical device placed in a container of any kind whose content can be variable, necessitating its weighing, counting or measuring at the time of sale.

3.11 Distributor, the person or entity that conditions or stores and distributes, and in the case of importation, for the commercialization of their goods, is in possession of a notice of performance or Health License depending on the nature of the products being sold.

3.12 Primary packaging, the elements of the container-closure system that are in direct contact with the medical device.

3.13 Secondary packaging, the items that are part of the package in which the medical device is marketed, and are not in direct contact with the device itself.

3.14 Multiple or collective container or packaging, any container or wrapping in which two or more primary or secondary packaging is contained.

3.15 Medical equipment, or the devices, accessories and equipment for specific use, intended for medical, surgical or examination procedures, diagnosis, treatment and rehabilitation of patients, as well as those intended to conduct biomedical research.

3.16 Label, full label, tag, inscription, mark or graphic image that has been written, printed, stencilled, marked, embossed or engraved, adhered or sealed in any material that may contain the medical device including the container itself.

3.17 Expiration date, the date indicated on the box or package, which is determined based on the life span of products subject to this rule. It is calculated according to the date of manufacture or sterilization of the medical device, where applicable.

3.18 Dental supplies, all substances or materials used for dental care.

3.19 Instructions, insert or leaflet, the document that in written or graphical form, or both, explains to the user the correct utilization or any other important information about the medical device, and that acts as a supplement to the Label and the Back label.

3.20 Lot, the specific amount of any medical device that is manufactured in one production cycle, under equivalent operating conditions in a given period of time.

3.21 Manual, the document that in written or graphical form, or both, explains to the user the installation, operation, maintenance or any other important information about the medical device.

3.22 Maquila (manufacture of accessory or intermediate products), the process or stage of a process involved in the fabrication of a medical device, performed by an establishment other than
the holder of the sanitary registration, whether they are national, international, temporary or permanent.

3.23 Surgical and healing materials, the devices or materials that may or may not contain antiseptics or germicides used in surgical practice or in the treatment of continuity solutions, skin lesions or its annexes.

3.24 Orthoses, the device or orthopedic brace which is used to support, align, prevent or correct deformities or to improve function of movable body parts.

3.25 Expiration date or period of useful life, the time interval in which a product, contained in the marketing container and stored under the recommended conditions that have been established based on stability studies, retains its correct specifications.

3.26 Caution, the legend or instruction that is placed on a medical device in order to avoid the harming or endangering the user during the use of the product.

3.27 Sanitary products, the materials and substances that are applied to the skin surface or body cavities, and that possess pharmacological or preventive action.

3.28 Prosthesis, the replacement of a missing part of the body that is used for functional reasons, aesthetics or both.

3.29 Symbol, the design or graphic that complements or replaces information to be provided to user.

3.30 Holder of the health registration certificate, the person or entity who holds an authorization granted by the Ministry of Health for the manufacture, importation, distribution or marketing of a medical device.

4. Health Information

4.1 The data displayed on the product labels or back labels of the products covered in this Standard, its sales packaging (primary, secondary, multiple or collective, as well as advertising contained within), shall comply with the provisions of Articles 2, sections III and IV, 17 bis, sections III and VII, 194, Section II, 194 bis, 195, 210, 212, 213, 214, 263, 264, 265 and 266 of the General Health Law, 2, section VIII, 7, section IV, 8, first paragraph, 9, 11, 15, 16, 23, 24, 165, 179 sections II, III and IX, 182, 183, Section III, Paragraph 184 seconds, 190, 205, Regulations for Health Inputs and 7, 8, 9, 52, 54, 55 and 56 of the Regulation of the General Health Law on advertising, and by any statutory provision applicable to the matter and expressed in Spanish in understandable and readable terms, or that is expressed in another language or other measurement system.

When information is expressed in a language other than Spanish, this may be of the same font size and proportion, not opposing or contravening the Spanish text. When the label of origin does not partly or wholly satisfy this standard, you can place a back label with full or complementary health information, displayed clearly and legibly in a conspicuous place, thus satisfying the mandatory minimum requirements; in cases where the original label stating health information is in accordance with this standard, it shall not be required to declare it again in the back label. The back should not contain health information that compromises the quality of the product, its use or both.
4.1.1 Minimum health information required for medical devices to be compliant with this Standard.

4.1.1.1 Generic product name

4.1.1.2 Distinctive product name. This is the only labeling requirement that is allowed to be expressed in a language other than Spanish, if this is the case.

4.1.1.3 Manufacturing data

4.1.1.3.1 The procedure for the expression of the manufacturing conditions and marketing should be:

4.1.1.3.1.1 Where the manufacturer in Mexico is the owner of the sanitary registration then the legend shall read:
"Hecho en (country) por:" or “Fabricado en (country) por:” or “Manufacturado en (country) por:”, or similar, followed by the name and address.

4.1.1.3.1.2 For imported products the legend shall read:
"Hecho en (country) por:" or “Fabricado en (country) por:” o “Manufacturado en (country) por:”, or other analogous statement, followed by the name and address.
“Importado” and/or “acondicionado” and/or “distribuido”, as appropriate, "por" followed by the name and address.

4.1.1.3.1.3 In the case of national or international maquila (manufacture of accessory or intermediate materials), the legend shall read:
"Hecho en (country) por:" or “Fabricado en (country) por:” o “Manufacturado en (country) por:”, or other analogous statement, followed by the name and address.
"Para:" followed by the name and address.

4.1.1.3.1.4 In the address should appear the following or equivalent information: street name and number, city, state, zip code and country.

4.1.1.4 Country of origin.
Legend identifying the country of origin of the product or its accessory, in accordance with the provisions of current regulations and international treaties of which Mexico is a part.

4.1.1.5 Registration Number issued by the Ministry of Health.

4.1.1.6 Product Expiration Date established in agreement with the stability studies, and not to exceed five years.
This applies to sterile products, and those which are included in the criteria specified by the corresponding Official Mexican Standard. In its identification the following legends should be used: "Caducidad y/o Expiración y/o Vencimiento o Cad. y/o Exp. y/o Venc." or other analogous statement or symbol. The identification of the expiration date must include the month and year in such a manner so as not to cause confusion to the user, in legible and indelible characters.

4.1.1.7 Lot or serial number.
Anywhere in the box or primary packaging, secondary and multiple or collective (if the latter exists), the following must appear on all products subject to this Standard: the lot identification or serial number with its code or in clear language, recorded and marked with indelible ink.
or other similar method established by the company. For identification, the following legends should be used: “Lote ___” o “Lot. ___”, “Número de serie ___” o “Serie No. ___” or analogous statement or symbol.

4.1.1.8 Content.
Indicate the number of units that it is composed of, dimensions, volume, corresponding weight, number of tests or applications, as applicable in each case. In the case of products, systems or equipment in collective packaging groups it is required to declare the contents according to the generic name of the components.

4.1.1.9 Instructions for use of the medical device.
When the use and preservation of the product is required, this information must be included, which is indicated on the label or back label or in the instructions or the manual annex, in which case it should refer to the respective label or back label with the words: "Léase instructivo anexo", "Léase inserto anexo", "Léase prospecto anexo", or analogous statement or symbol.

4.1.1.9.1 In the specific case of powdered culture media, the method of preparation and final pH should be included on the label, back label, instruction sheet or insert.

4.1.1.10 All adverse incidents that could occur during the use or application of the product must be reported on the label or back label. For those products which by their nature or size cannot contain this information, then it should be indicated in the instruction manual.

4.1.1.11 Warning legends, cautions or both must be declared when the characteristics of the medical device require it.

4.1.1.11.1 In the case of toxic or hazardous materials, warning legends or caution statements are subject to the provisions of relevant existing regulations.

4.1.1.11.2 In the case of equipment and diagnostic agents involving radiation sources the legend must read: “Peligro, material radiactivo para uso exclusivo en medicina”; must indicate the active isotopes, their half lives and the types of radiation emitted, using the internationally recognized symbol for radioactive materials.

4.1.1.12 For sterile products the following or similar legend or symbol should be included: “Producto estéril”, "No se garantiza la esterilidad del producto en caso de que el empaque primario tenga señales de haber sufrido ruptura previa", and legends or symbols indicating the sterilization process such as: “Esterilizado con óxido de etileno”, “Esterilizado con radición gamma”, “Esterilizado con calor seco o húmedo”, “Procesados usando técnicas asépticas” or other analogous statement.

4.1.1.13 "Nontoxic," "pyrogen free" or other allusive legends where appropriate.

4.1.1.14 Products that are not reusable should indicate this by using the legends “Desechable”, “Usar solamente una vez”, or other analogous legends or symbols that are located on the unit that is received by the end user.

4.1.1.15 Symbols for units of measurement.
It should use the units of the General System of Measurement Units and °C, as established in NOM-008-SCFI-2002, where appropriate.
4.1.1.15.1 When the product characteristics require storage at a specific temperature, humidity condition or other special condition such as protection from solar radiation, that must be stated and expressed in ° C on the label or the corresponding back label.

4.1.1.16 Medical devices that based on their characteristics and composition have multiple ingredients should indicate those ingredients, using a qualitative formula or declaration of its principle active ingredients or drugs contained therein, on the label or the back label.

4.1.1.16.1 This information may be included in the instruction manual when the product size makes it impossible to include it on the label or the back label.

4.1.1.16.2 The medical device marketed as a kit, system or package must have in their label or back label a declaration of the components comprising this presentation.

4.1.1.17 Products which by their nature or the size of the units that are dispensed may not contain a label or back label, or when because of its size it may not contain all of the data specified in the preceding paragraphs, must contain at least the following information:

4.1.1.17.1 Generic name
4.1.1.17.2 Distinctive name.
4.1.1.17.3 Lot Number
4.1.1.17.4 The expiration date, if applicable.
4.1.1.17.5 Content, except where this is obvious.

4.1.1.18 Diagnostic agents for use in vitro.

4.1.1.18.1 Medical devices in this category should indicate this through the use of the legend “Agente de diagnóstico”.

4.1.1.18.2 The device should include the legend “Para uso exclusivo en Laboratorios Clínicos o de Gabinetes” when the diagnostic agents are intended for use in medical devices or equipment located in clinical laboratories or laboratory units in hospitals.

4.1.1.18.3 Any part of the primary, secondary or group packaging can include catalog identification, for information and reference only, indicating a code or in plain language, whether engraved, marked with indelible ink or other similar method established by the company.

4.1.1.19 Medical devices intended for the health sector can include the code or description of the Cuadro Básico (Basic Chart) and the Catálogo de Insumos del Sector Salud (Catalogue of Health Sector Ingredients) corresponding to the specific medical device in the label or the back label.

4.1.1.20 The information contained on the labels or back labels should correspond to that which was submitted and authorized by the Ministry of Health, in accordance with the applicable provisions and may not be modified.

4.1.1.21 Indicated in the previous sections is the minimum information that must be declared, always allowing for the inclusion of additional information as long as it does not cause confusion, as appropriate with the characteristics of the product and provided that it has been approved by the Ministry of Health.
4.1.1.22 The use of additional symbols other than those included in standard Appendix A is permitted, provided that its inclusion and meaning does not confuse the customer and that its use is justified.

4.1.1.23 The labels or back labels containing the above information may be incorporated into the imported product, now on national territory, after customs clearance and before marketing or supply to the public.

4.1.1.24 For bulk medical devices the labeling of origin is only required for multiple (collective) packages, and must contain at least the following information:

4.1.1.24.1. Generic name
4.1.1.24.2 Distinctive name
4.1.1.24.3 Lot number
4.1.1.24.4 The expiration date, if applicable.

4.1.1.25 When the medical device requires a specific software program to operate it, this program should declare the corresponding version.

4.1.1.26 You can optionally use the symbols listed in Appendix B

4.1.2 The product labeling, in addition to the above, must include the information specified in existing rules specific to the product or pharmacopoeia monographs as appropriate.

5. Compliance with international and Mexican standards

This Mexican Official Standard partially agrees with the following standard:

5.1 EN 980:2007 Graphical symbols for use in the labeling of medical devices.

6. Bibliography

6.1 General Health Law.
6.2 Federal Law on Metrology and Standardization.
6.4 Regulation of Health Supplies.
6.5 Regulation of the General Health Law on advertising.
6.6 Regulations of the Federal Law on Metrology and Standardization.
6.7 Regulation of the Federal Commission for Protection Against Health Risks.

7. Standard Compliance

The enforcement of this rule is the responsibility of the Ministry of Health, whose staff perform the verification and monitoring as necessary.

8. Conformity assessment

8.1 The conformity assessment of this standard will be made by the Secretariat through the Federal Commission for Protection Against Health Risks (COFEPRIS).
8.2 The conformity assessment of this standard may also be made by Third Parties, authorized under the terms of the General Health Law and Regulation of Health Supplies. In this case, the list of third parties authorized by the Secretariat will be available on the website of COFEPRIS: www.cofepris.gob.mx and in the offices of the Committee on Evidence and Risk Management, situated in Monterrey No. 33, 9 piso, Colonia Roma, Delegación Cuauhtemoc, Mexico, DF, CP 06 700.
8.3 The procedure for conformity assessment shall be as follows:
   8.3.1 In order to determine the degree of compliance with this standard the following verification shall be made by COFEPRIS’ technical inspectors, or third parties authorized in any of the following options:
      8.3.1.1 In the manufacturing sites of medical devices, in its stores, and in those of the Distributor, in accordance with the points covered in this Standard.
      8.3.1.2 During the period of application for a medical device registration, extension (renewal) or modification of the label (labeling), presented for the evaluation of COFEPRIS.
8.3.2 In any of the options provided in sections 8.3.1.1 and 8.3.1.2, the data contained either on the label or the back label of the medical device will be verified by COFEPRIS, as referred to in this Standard. In the case of new sanitary registrations, extension (renewal) or updating and modification to the original terms of the Health Record affecting the information initially authorized by COFEPRIS, the record (Dossier) submitted by the holder of health will be reviewed by the technical staff of this committee. Label changes that have been reviewed and approved, along with documents submitted for processing pursuant to paragraphs 8.3.1.1 and 8.3.1.2, will be returned to the owner of the health registration upon completion of the verification.
8.3.3 In any of the options provided in sections 8.3.1.1 and 8.3.1.2, a review or audit shall be carried out of the legends and/or symbols to used to describe the medical device as described in this standard.
9. Validity

This Standard will come into force sixty calendar days after its publication in the Official Journal of the Federation.

10. Appendix “A”

Symbols that can be used in place of their respective legends

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<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
<th>Reference number</th>
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<tr>
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<td>Expiration Date</td>
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<tr>
<td><img src="image" alt="Lot Number" /></td>
<td>Lot number</td>
<td>4.1.1.7</td>
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<tr>
<td><img src="image" alt="Serial Number" /></td>
<td>Serial number</td>
<td>4.1.1.7</td>
</tr>
<tr>
<td><img src="image" alt="Instructions" /></td>
<td>Instructions for use of the medical device</td>
<td>4.1.1.9 and 4.1.1.10</td>
</tr>
<tr>
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<td>Cautions or warnings</td>
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</tr>
<tr>
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</tr>
<tr>
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<td>Sterilized with ethylene oxide</td>
<td>4.1.1.12</td>
</tr>
<tr>
<td>Symbol</td>
<td>Description</td>
<td>Reference</td>
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<tr>
<td>--------</td>
<td>------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td><img src="image" alt="Sterile R" /></td>
<td>Sterilized with gamma radiation</td>
<td>4.1.1.12</td>
</tr>
<tr>
<td><img src="image" alt="Dry Heat" /></td>
<td>Sterilized with dry or humid heat</td>
<td>4.1.1.12</td>
</tr>
<tr>
<td><img src="image" alt="Aseptic" /></td>
<td>Medical devices processed using aseptic techniques</td>
<td>4.1.1.12</td>
</tr>
<tr>
<td><img src="image" alt="Single Use" /></td>
<td>Products for single use only</td>
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</tr>
<tr>
<td><img src="image" alt="Temperature Min" /></td>
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<tr>
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<tr>
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### Optional symbols for the identification of medical devices

<table>
<thead>
<tr>
<th>Symbol</th>
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<tbody>
<tr>
<td>IVD</td>
<td>Diagnostic agents for use in vitro</td>
</tr>
<tr>
<td>DIV</td>
<td>Catalogue identification, where applicable</td>
</tr>
<tr>
<td>REF</td>
<td>Radioactive</td>
</tr>
</tbody>
</table>

**Registration holder, responsible for fabrication whether that takes place in Mexico or abroad. Should not be confused with the information of the manufacturer or the product.**

**Manufacturing date**

**Only for performance evaluations for in vitro diagnostic products**

**Representative authorized by the European Union**

**Number of tests**
<table>
<thead>
<tr>
<th>Illustration</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td><img src="image" alt="Biohazard Icon" /></td>
<td>Infectious biological risk</td>
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<td>![Control Icon]</td>
<td>Control or verification</td>
</tr>
<tr>
<td>![Control Positive Icon]</td>
<td>Positive control or verification</td>
</tr>
<tr>
<td>![Control Negative Icon]</td>
<td>Negative control or verification</td>
</tr>
</tbody>
</table>

Attentively

México, D.F., the 3rd of September 2008. - El Comisionado Federal para la Protección contra Riesgos Sanitarios y Presidente del Comité Consultivo Nacional de Normalización de Regulación y Fomento Sanitario,  
**Miguel Angel Toscano Velasco**.- Rúbrica.