DOF: 12/12/2008

Oficial Mexican Standard NOM-137-SSA1-2008, Labeling of medical devices.

On the margin a seal with the National Shield, which says: United Mexican States – Ministry of Health.

OFFICIAL MEXICAN STANDARD NOM-137-SSA1-2008, LABELING OF MEDICAL DEVICES.

MIGUEL ANGEL TOSCANO VELASCO, Federal Commission for the Protection from Sanitary Risks and President of the National Consultative Committee for Standardization of Regulation and Sanitary Promotion, based on Articles 39 of the Organic Law of the Federal Public Administration; 4 and 69 H of the Federal Law of Administrative Procedure; 3, fraction XXV, 13 section A), fractions I and II, 17 bis, fractions II, III, VI and VII, 194, fraction II, 194 bis, 195, 210, 212, 212, 213, 214, 262, 263, 264, 265 and 266 of the General Health Law; 3, fraction XI, 38, fraction II, 40, fractions I, V, XI and XII, 41, 43, 47, 51, 52 and 62 of the Federal Law on Metrology and Standardization; 2, fraction VIII, 7, fractions III and IV, 8, first paragraph, 9, 11, 15, 16, 23, 24, 27,165,179, fractions II, III and IX, 182, 183, fraction III, 184, second paragraph, 190 and 205 of the Regulations of Health Supplies; 28, 33 and 39 of the Regulations of the Federal Law on Metrology and Standardization, 2, subsection C, fraction X and 36 of the Internal Regulations of the Ministry of Health, and 3, fractions I and II of the Regulation of the Federal Commission for Protection from Sanitary Risks, I am pleased to issue and ordered of the Official Mexican Standard NOM-137- SSA1-2008, Labeling of medical devices, in the Official Gazette of the Federation.

WHEREAS

On July 26, 2005, in compliance with the provisions of Article 46 fraction I of the Federal Law on Metrology and Standardization, the Federal Commission for the Protection from Sanitary Risks presented to the National Consultative Committee for Standardization of Regulation and Sanitary Promotion, the preliminary draft of the present Official Mexican Standard.

On April 25, 2008, in compliance with the agreement of the Committee and the provisions of Article 47 fraction I of the Federal Law on Metrology and Standardization, the draft of the present Official Mexican Standard was published in the Official Gazette of the Federation, so that within the following sixty calendar days after such publication, interested parties may submit their comments to the National Consultative Committee for Standardization of Regulation and Sanitary Promotion.

On a previous date, the responses to the comments received by the

aforementioned Committee were published in the Official Gazette of the Federation, in the terms of article 47 fraction III of the Federal Law on Metrology and Standardization.

In attention of the above considerations, and with the approval of the National Consultative Committee for the Standardization of Regulation and Sanitary Promotion, the following is issued:

OFFICIAL MEXICAN STANDARD NOM-137-SSA1-2008, LABELING OF MEDICAL DEVICES

PREFACE

The institutions below and organizations participated in the development of this Mexican Official Standard:

SECRETARIA DE SALUD.

DIRECCION GENERAL DE ASUNTOS JURIDICOS.

COMISION FEDERAL PARA LA PROTECCION CONTRA RIESGOS SANITARIOS.

CENTRO NACIONAL DE EXCELENCIA TECNOLOGICA EN SALUD.

CONSEJO DE SALUBRIDAD GENERAL.

Comisión Interinstitucional del Cuadro Básico de Insumos del Sector Salud.

INSTITUTO MEXICANO DEL SEGURO SOCIAL.

INSTITUTO DE SEGURIDAD Y SERVICIOS SOCIALES DE LOS TRABAJADORES DEL ESTADO.

UNIVERSIDAD NACIONAL AUTONOMA DE MEXICO.

Programa Universitario de Investigación en Salud.

INSTITUTO POLITECNICO NACIONAL.

Escuela Superior de Medicina.

COMISION PERMANENTE DE LA FARMACOPEA DE LOS ESTADOS UNIDOS MEXICANOS.

CAMARA NACIONAL DE LA INDUSTRIA DE LA TRANSFORMACION.

Sector Industrial Médico.

CAMARA NACIONAL DE LA INDUSTRIA FARMACEUTICA.

Sección de Productos Auxiliares para la Salud-Dispositivos médicos.

Sección de Reactivos y Sistemas de Diagnóstico.

CAMARA NACIONAL DE LA INDUSTRIA DE ACEITES, GRASAS, JABONES Y DETERGENTES.

CAMARA NACIONAL DE LA INDUSTRIA DE PERFUMERIA, COSMETICA Y ARTICULOS DE TOCADOR E HIGIENE.

ACADEMIA NACIONAL DE CIENCIAS FARMACEUTICAS.

ASOCIACION FARMACEUTICA MEXICANA, A.C.

COLEGIO NACIONAL DE QUIMICOS FARMACEUTICOS BIOLOGOS, MEXICO, A.C.

PRODUCCION QUIMICO FARMACEUTICA, A.C.

ASOCIACION MEXICANA DE LABORATORIOS FARMACEUTICOS, A.C.

ASOCIACION MEXICANA DE INDUSTRIAS INNOVADORAS DE DISPOSITIVOS MEDICOS, A.C.

INDEX

1. Objective and field of application

1.1 Objective

This Official Mexican Standard establishes the minimum requirements, which serve to communicate the information to users, which must contain the labeling of medical devices (medical equipment, prostheses, orthoses, functional aids, diagnostic agents, dental supplies, surgical and healing materials and hygienic products) of national or foreign origin, which are marketed or intended for users in the national territory.

1.2 Application field

This Official Mexica Standard is mandatory for all establishments dedicated to the manufacture, conditioning, import and distribution of medical devices.

2. References

For the correct application of this Mexican Official Standard, it is convenient to consult the following standards:

2.1 NOM-008-SCFI-2002. General System of Units of Measurement. Published in the Official Gazette of the Federation on November 27, 2002.
2.2 NOM-050-SCFI-2004. Commercial information-General product labelling. Published in the Official Gazette of the Federation on June 1, 2004.
2.3 Pharmacopoeia of the United Mexican States and its Supplements

3. Definitions

For the purposes of this Official Mexican Standard:

3.1 Conditioning, the necessary operations that a bulk product must go through to reach its presentation as a finished product.
3.2 Warning, the writing or legend with indications to warn the user from the risk of using a medical device.
3.3 Diagnostic Agent, all supplies including antigens, antibodies, calibrators, verifiers or controls, reagents, reagent equipment, culture and contrast media and any other similar that can be used as an auxiliary to other clinical or paraclinical procedures.
3.4 Functional Aids, inputs without pharmacological properties that help to improve a function of the organism.
3.5 Storage conditions, to all those conditions resulting from the development of medical device stability tests.
3.6 Back label, the label that contains the complementary or total minimum mandatory health and commercial information, when the label of origin does not partially or totally comply with this standard.
3.7 Distinctive name, The name assigned as a trademark by the laboratory or manufacturer to its medical devices 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 that have common characteristics, accepted by the health authority.
3.9 Medical device, the substance, mixture of substances, material, apparatus or instrument (including the software necessary for its proper use or application), used alone or in combination in the diagnosis, monitoring or prevention of disease in humans or auxiliaries in the treatment of diseases and disability, as well as those used in the replacement, correction, restoration or modification of human anatomy or physiological processes. Medical devices include products in the following categories: medical equipment, prostheses, orthoses, functional aids, diagnostic agents, dental supplies, surgical and healing materials and hygienic products.

3.10 **Medical device in bulk**, The medical device placed in a container of any nature and whose content may be variable and must be weighed, counted or measured at the time of sale.

3.11 **Distributor**, the natural or legal person that conditions or stores and distributes, and, where appropriate, imports goods for commercialization, that it has an operating license or sanitary license, depending on the type of products that it commercializes.

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

3.13 **Secondary packaging**, the elements that are part of the packaging in which the medical device is marketed and that are not in direct contact with it.

3.14 **Multiple or collective packaging**, to any container or wrapper in which two or more primary or secondary containers are contained.

3.15 **Medical equipment**, devices, accessories and instruments for specific use, intended for medical or surgical care or procedures for the exploration, diagnosis, treatment and rehabilitation of patients, as well as those for as well as those to carry out biomedical research activities.

3.16 **Label**, Any tag, label, inscription, mark, brand or graphic image that has been written, printed, stencilled, marked, embossed, debossed, stamped, stamped, adhered or sealed on any material likely to contain the medical device, including the container itself.

3.17 **Expiration date**, at the date indicated on the container or package, which is determined based on the shelf life of the products covered by this standard. It is calculated from the date of manufacture or sterilization of the medical device, as applicable.

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

3.19 **Instructional, insert or package leaflet**, the document that in written or graphic form, or both, that explains to the user the use or any other important information of the medical device and that is additional to the label or back label.

3.20 **Lot,** the specific quantity of any medical device, which has been produced in a production cycle, under equivalent operating conditions and for a specified period.

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

3.22 **Manufacturing**, the process or stage of a process involved in the manufacture of a medical device carried out by an establishment other than the holder of the sanitary registration, can be national, international, temporary or permanent.

3.23 **Surgical and healing material**, to devices or materials that added or not of antiseptics or germicides are used in surgical practice or in the treatment of continuity solutions, skin lesions or their annexes.

3.24 **Orthosis**, an orthopedic device or appliance used to support, align, prevent or correct deformities or to improve the function of moving parts of the body.

3.25 **Shelf-life**, The time interval in which a product contained in the marketing container and under the storage conditions established on the basis of stability studies remains within specifications.

3.26 **Caution**, the legend or instruction that is placed on a medical device in order to avoid the user harm or danger in the use of the product.

3.27 **Hygienic products**, the materials and substances which are applied to the surface of the skin or body cavities and which have pharmacological or preventive action.

3.28 **Prosthesis**, a substitute for a missing part of the body that is used for functional, aesthetic or both reasons.

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

3.30 **Sanitary Registration Holder**, the natural or legal person who holds the authorization granted by the Ministry of Health for the manufacture, import, distribution or marketing of a medical device.

4. Health information

4.1 The data held by the labels or back labels of the products subject to this Standard, in their packaging or sales packaging (primary, secondary, multiple or collective, as well as the advertising contained therein, must comply with the provisions of the Articles 2, fractions III and IV, 17 bis, fractions III and VII, 194, fraction II, 194a, 195, 210, 212, 213, 214, 263, 264, 265 and 266 of the General Health Law 2, fraction VIII, 7, fraction IV, 8, first paragraph, 9, 11, 15, 16, 23, 24, 165, 179 fractions II, III and IX, 182, 183, fraction III, 184 second paragraph, 190, 205, of the Regulation on Health Supplies and 7, 8, 9, 52, 54, 55 and 56 of the Regulation of the General Health Law on Advertising, as well as by any legal provision applicable to the matter and will be expressed in Spanish in their content in understandable and legible terms, without prejudice to their being expressed in other languages or other system of measurement.

When the information is expressed in another language in addition to Spanish, it may be up to the same size and typographic proportionality, without opposing or contravening the text in the Spanish language. When the label of origin does not comply partially or totally with this Standard, a back label with the total or complementary information of the minimum mandatory sanitary type may be placed in a clear and legible manner and be placed in a visible place; in those cases where the original label declares the health information in accordance with the provisions of this standard,

it will not be mandatory to declare it again on the back label. The back label must not cover health information that compromises the quality of the product, its use or both.

4.1.1 Mandatory minimum sanitary information for medical devices subject to compliance with this Standard.

4.1.1.1 Generic name of the product

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

4.1.1.3 Manufacturer's details

4.1.1.3.1 The modalities for the expression of the manufacturing and marketing conditions shall be:

4.1.1.3.1.1 When the manufacturer in Mexico is the holder of the sanitary registration, the legend shall be expressed:
"Made in Mexico by:" or "Fabricated in Mexico by:" or "Manufactured in México by:", or similar followed by the business name and address.

4.1.1.3.1.2 For imported products, the legend shall be expressed:
"Made in (country) by:" or "Fabricated in (country) by:" or "Manufactured in (country) by:", or similar followed by the business name and address.
"Imported" and/or "conditioned" and/or "distributed", as the case may be, "by" followed by the company name and address.

4.1.1.3.1.3 In the case of national or international massive manufacturing process, the legend will be expressed:
"Made in (country) by:" or "Fabricated in (country) by:" or "Manufactured in (country) by:", or similar followed by the business name and address.
"To:" followed by the company name and address.

4.1.1.3.1.4 The address must include the following information or its equivalent: street name, number, neighborhood, city, state, zip code and country.

4.1.1.4 Country of origin.
A legend that allows to identify the origin country of the product or name in accordance with the provisions of current regulations and international treaties to which Mexico is a party.

4.1.1.5 Registration number granted by the Ministry of Health.

4.1.1.6 Expiration date of the product, when applicable, according to stability studies, which should not exceed 5 years. Applies to sterile products, and to those included in the criteria specified in the corresponding Official Mexican Standard. For its identification, the following allusive legends must be used: "Expiration and / or Expiration and / or

Expiration or Cad. and/or Exp. and/or Venc." or another analogue or the corresponding symbol. The identification of the expiration date must include the month and year in such a way that it does not cause confusion in the user, in legible and indelible characters.

4.1.1.7 Lot number or serial number.

In any part of the primary, secondary and multiple or collective packaging (as long as the latter exists), shall appear on all products covered by this Standard, the identification of the lot or serial number with an indication in code or in clear language, whether engraved, marked with indelible ink or in any other similar way, established by the company itself. For identification, the following allusive legends must be used: "Lot ___" or "Lot. ___", "Serial number ___" or "Serial No. ___" or other similar or the corresponding symbol.

4.1.1.8 Content

Indicate the number of units that compose it, nominal dimensions, volume, the corresponding weight, number of tests or applications, as applied in each case. In the case of products, systems or equipment in collective packaging, the content must be declared according to the components that integrate it by generic denomination.

4.1.1.9 Instructions for use of the medical device

When required by the use, handling and conservation of the product, this information must be available and indicated on the label or back label, or in the accompanying instructions or manual in which case reference must be made on the respective label or back label by the legend "Read instructions annex", "Read insert annex", "Read annex leaflet", or allusive legends or the corresponding symbol.

4.1.1.9.1 For the specific case of powdered culture media, the method of preparation and final pH should be included on the label, back label, instructions for use or insert.

4.1.1.10 Any adverse incident that may result from the use of the product, when applicable, must be reported on the label or back label. For those products that, due to their nature or size, cannot incorporate it, this information may be indicated in the instructions for use.

4.1.1.11 Warning or caution legends or both should be declared when the characteristics of the medical devices so require.

4.1.1.11.1 In the case of toxic or dangerous products, their warning legends or precautionary reports must be subject to the provisions of the corresponding regulations.

4.1.1.11.2 In the case of equipment and diagnostic agent involving radiation sources, declare the legend: “Danger, radioactive material for medical use only"; the indication of the isotopes containing activity, their half-life and type of radiation emitted, as well as the international logo recognized to indicate radioactive materials.

4.1.1.12 For sterile products, the following or similar legends or the corresponding symbol must be included: "Sterile product", "The sterility of the product is not guaranteed in case the primary packaging shows signs of having suffered previous rupture", and the allusive legends or the corresponding symbol indicating the sterilization process such as: "Sterilized with ethylene oxide", "Sterilized with gamma radiation", "Sterilized with dry or wet heat", "Processed using aseptic techniques" or other similar techniques.

4.1.1.13 "Non-toxic", "pyrogen-free" or allusive legends, when applicable.

4.1.1.14 The products to be used only once, must indicate this situation by using the legends "Disposable", "Use only once", or other allusive legends or corresponding symbol, on the unit purchased by the end user.

4.1.1.15 Symbols for units of measurement.

The units of the General System of Units of Measurement and degrees °C must be used, in accordance with the provisions of NOM-008-SCFI-2002, when applicable.

4.1.1.15.1 When the characteristics of the product require special storage temperatures, these must be indicated and expressed in degrees °C, as well as the special humidity conditions required by the product or any other specific condition, when applicable, such as light protection, which shall be indicated on the corresponding label or back label.

4.1.1.16 Formulated medical devices that, based on their characteristics and composition, have several ingredients must have on their label or back label the qualitative formula or the declaration of their active ingredients or drugs contained, when applicable.

4.1.1.16.1 This information may be included in the instructions for use when due to the size of the product it is not possible to include it on the label or back label.

4.1.1.16.2 Medical devices marketed as a kit, system or package must have on their label or back label the declaration of the components that make up that presentation.

4.1.1.17 Products which, due to their nature or the size of the units in which they are sold or supplied, cannot bear a label, back label or when, due to their size, they cannot contain all the data indicated in the previous paragraphs, must contain at least the following data:

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, when applicable.

4.1.1.17.5 Content, except when obvious.

4.1.1.18 Diagnostic agents for in vitro use.

4.1.1.18.1 Medical devices included in this category must indicate this condition by using the legend "Diagnostic Agent".

4.1.1.18.2 They must include the legend "For use only in Clinical laboratories or cabinets" only when diagnostic agents are used in medical devices or equipment located in clinical laboratories or laboratory units in hospitals.

4.1.1.18.3 In any part of the primary, secondary or multiple packaging or packaging, the identification of the catalog may be included, for informative and referential purposes exclusively, with an indication in code or in clear language, whether engraved, marked with indelible ink or in any other similar way, established by the company itself.

4.1.1.19 Medical devices intended for the health sector may include on the label or back label the code or description of the current Basic List and Catalog of Health Sector Supplies corresponding to the medical device.

4.1.1.20 The information contained in the labels or back labels must correspond to what is expressed in the marbete projects authorized by the Ministry of Health in accordance with the applicable provisions and may not be modified.

4.1.1.21 The information indicated in the previous points corresponds to the minimum mandatory information to be declared, allowing the inclusion of additional information as long as it is not confusing, corresponds to the characteristics of the product and has been authorized by the Ministry of Health.

4.1.1.22 The use of symbols in addition to those included in Regulatory Appendix A is permitted, provided that their inclusion and meaning does not represent confusion to the consumer and their use is justified.

4.1.1.23 The labels or back labels containing the above information may be incorporated into the import product, already in national territory, after customs clearance and before its marketing or supply to the public.

4.1.1.24 For bulk medical devices only origin labeling is required on the multipack (collective) which 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, and

4.1.1.24.4 The expiration date, when applicable.

4.1.1.25 When the medical device requires a specific computer program in order to perform its operation, this program must declare the corresponding version.

4.1.1.26 The symbols included in informative Appendix B may be used optionally.

4.1.2 The labelling of the products, in addition to the above, must include the information indicated in the current product-specific rules or the pharmacopeial monographs as appropriate.

5. Conformity with international and Mexican standards

This Official Mexican Standard is partially consistent with the following standard:

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

6. Bibliography

6.1 General Health Law.

6.2 Federal Law on Metrology and Standardization.

6.3 Federal Consumer Protection Law.

6.4 Regulation of Health Supplies.

6.5 Regulation of the General Health Law on Advertising.

6.6 Regulation of the Federal Law on Metrology and Standardization.

6.7 Regulation of the Federal Commission for Protection from against Sanitary Risks.

6.8 Guidance for industry and FDA staff. Use of symbols on labels and in labeling of in vitro diagnostic devices intended for professional use.- Washington, Food and Drug Administration, noviembre 2004.

6.9 Code of Federal Register Part 91-4179 Medical Device Good Manufacturing Practices Manual.- Washington, Food and Drug Administration, abril 2004.

6.10 Global Harmonization Task Force. GHTF/SG1/N43:2005 Labeling of medical equipment and devices.- 2005.

6.11 Latex labeling required for medical devices. Talk Paper Food and Drug Administration US Department of Health and Human Services. Septiembre 1997.

7. Observance of the Standard

The monitoring of compliance with this Standard corresponds to the Ministry of Health, whose staff will carry out the necessary verification and monitoring.

8. Conformity assessment

8.1 The conformity assessment of this Standard shall be carried out by the Ministry through the Federal Commission for the Protection from against Sanitary Risks (COFEPRIS).

8.2 The conformity assessment of this Standard may also be carried out by Authorized Third Parties, under the terms of the General Health Law and the Regulation of Supplies for Health.

In this case, the list of Third Parties Authorized by the Ministry will be available on the website of the COFEPRIS, www.cofepris.gob.mx, as well as in the offices of the Evidence and Risk Management Commission located at Monterrey No. 33, 9 piso, colonia Roma, Delegación Cuauhtémoc, México, D.F., C.P. 06700.

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, verifications will be carried out by Technical Inspectors of COFEPRIS, or by authorized Third Parties in any of the following options:

8.3.1.1 At medical device manufacturing sites, at their warehouses and at the Distributor's warehouses, in accordance with the items covered in this Standard.

8.3.1.2 During the application for sanitary registration of a medical device, extension (renewal) or modification of the same through the projects of marbete (labeling), submitted for evaluation to COFEPRIS.

8.3.2 In any of the options provided for in paragraphs 8.3.1.1 and 8.3.1.2, the verification of the data contained in either the label

or back label of the medical device against what is approved by COFEPRIS will be carried out, according to what is referred to in this Standard. In the case of new Sabitary Registrations, extension (renewal) or update as well as modification to the original conditions of the Sanitary registration that affect the information initially authorized by COFEPRIS, through the review of the File (dossier) presented by the holder of the sanitary registry, by the technical staff of this Commission.

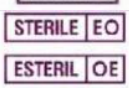
The revised and approved marbete projects or, where appropriate, the final label together with the documents submitted for processing in accordance with paragraphs 8.3.1.1 and 8.3.1.2 will be returned to the holder of the Sanitary Registry once the corresponding verification has been completed.

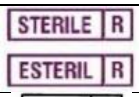
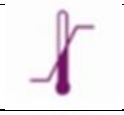
8.3.3 In any of the options provided for in paragraphs 8.3.1.1 and 8.3.1.2, the review or verification of the legends and / or symbols to be used in the medical device described in this Standard will be carried out.

9. Validity This Standard will enter into force sixty calendar days after its publication in the Official Gazette of the Federation.

10. Normative Appendix "A".

Symbols that can be used in substitution of the respective legends.

Symbol	Expresses	Referred Numeral
	Expiration date	4.1.1.6
	Lot number	4.1.1.7
	Serial number	4.1.1.7
	Instructions for use of the medical device	4.1.1.9 y 4.1.1.10
	Warnings or cautions	4.1.1.11
	Sterile product	4.1.1.12
	Sterilized with ethylene oxide	4.1.1.12

	Sterilized with gamma radiation	4.1.1.12
	Sterilized with dry or moist heat	4.1.1.12
	Medical devices processed by aseptic techniques	4.1.1.12
	One-time use products	4.1.1.14
	Minimum temperature	4.1.1.15.1
	Temperature range	4.1.1.15.1
	Maximum temperature	4.1.1.15.1
	Diagnostic agents for in vitro use	4.1.1.18.1
	Catalog identification, where applicable	4.1.1.18.3
	Radioactive	4.1.1.11.2

11. Informative Appendix “B”

Optional symbols for the identification of medical devices.

Symbol	Expresses
	Holder of the product and legally responsible for manufacturing, whether in Mexico or abroad. Not to be confused with the data of the manufacturer, maquilador, processor or assembler of the product.
	Date of manufacture

	Performance evaluation for in vitro diagnostic products only.
	Authorized representative in the european community
	Number of tests
	Infectious biohazard
	Control or verifier
	Positive control or verifier
	Negative control or verifier

Attentively

Mexico City, September 3, 2008 - The Federal Commission for the Protection from Sanitary Risks and President of the National Consultative Committee for the Standardization of Regulation and Sanitary Promotion, Miguel Angel Toscano Velasco - Rubric.