JOINT BOARD OF DIRECTORS RESOLUTION NO. 37, OF AUGUST 26, 2015

Concerning the standardizing of sentences declaring natural rubber latex content in medical device labeling.

The Joint Board of Directors of the Brazilian Health Surveillance Agency (ANVISA), in exercise of the powers conferred by items III and IV of Art. 15 of Law No. 9.782 of January 26, 1999, of item V and paragraphs 1 and 3 of Art. 58 of its Internal Regulations approved as per the terms of Annex I of Joint Board of Directors Resolution - RDC No. 29 of July 21, 2015 published in the Federal Official Gazette of July 23, 2015, considering the provisions of item III of Art. 2, items III and IV of Art. 7 of Law No. 9.782 of 1999, and the Agency's Regulation Process Improvement Program, instituted by Ordinance No. 422 of April 16, 2008, and as agreed to at a meeting held on August 20th, 2015, hereby adopts the following Joint Board of Directors resolution, and I, as current Chairman, order its publication:

Art. 1 This Regulation establishes standard sentences to be used on the labels of medical devices that contain natural rubber latex.

Art. 2 This Regulation is applicable to the following medical devices:

I- Medical products – health products, such as equipment, devices, material, articles or systems for medical, dental, laboratory, or esthetic use or applications used for prevention, diagnoses, treatment, rehabilitation, or contraception, and which do not use pharmaceutical, immunological, or metabolic means to achieve their primary function in humans, but whose functions may, however, be assisted by such means;

II- In-vitro diagnostic products: reagents, calibrators, standards, controls, sample collectors, materials and instruments used individually or in combination, whose intended use is determined by the manufacturer, used to perform in-vitro analyses of samples derived from the human body, used exclusively or principally to provide information regarding diagnostics, monitoring, screening or to determine compatibility with potential blood, tissue and organ recipients.

Art. 3 Labels of medical devices containing natural rubber latex must contain the following highlighted standard sentence: "THIS PRODUCT CONTAINS NATURAL RUBBER LATEX".

§1 - The use of the expression "hypoallergenic" in medical device labeling is prohibited.

§2 – The sentence appearing in Art. 17 of the Joint Board of Directors Resolution - RDC No. 55, of November 4, 2011 may be used for surgical gloves and non-surgical procedure gloves made of natural rubber, synthetic rubber, a mixture of synthetic and natural rubber or polyvinyl chloride, when subject to sanitary surveillance.

Art. 4 In substitution of the sentence "THIS PRODUCT CONTAINS NATURAL RUBBER LATEX", a symbol identifying the presence of natural rubber latex may be used, in accordance with technical note ABNT NBR ISO 15223-1:2013 – Health products – Symbols to be used on labels, labeling, and information on health products that must be provided – Part 1: General requirements: or technical standards that may replace them.

Sole Paragraph. On medical device labels that use a symbol to identify the presence of natural rubber latex, there must appear, next to the symbol, the following standard phrase: "THIS PRODUCT MAY CAUSE ALLERGIC REACTIONS."

Art. 5 The medical device labels covered by this Resolution should be updated within 365 (three hundred and sixty five) days of the date of its publication.

Art. 6 Products manufactured before the date this Resolution enters into force, or during the adjustment period described in Art. 5 above may be commercialized and used up to their date of expiry.

Art. 7 Non-compliance with legal provisions established herein represents a sanitary violation, pursuant to the terms of Law no. 6437, of August 20th, 1977, notwithstanding other applicable civil, administrative and criminal responsibilities.

Art. 8 This Resolution shall come into force on the date of its publication.

"ANEXO III

QUADRO DEMONSTRATIVO DE CARGOS EM COMISSÃO E DE CARGOS COMISSIONADOS TÉCNICOS