RESOLUTION RDC No. 34, JUNE 15th, 2012

Changes RDC 206, of November 17th, 2006, which establishes the technical regulation on in-vitro diagnostic products and their registro and cadastro registration, as well as registration changes, revalidations, and cancellations.

The Collegiate Board of Directors of the Brazilian National Health Surveillance Agency (ANVISA), in the exercise of the powers vested by Article 11, subsection IV, of ANVISA Regulation approved by Decree no. 3,029, of April 16th, 1999, and in view of the provisions of Article 54, subsection II, paragraphs 1 and 3, of the Internal Statute approved under the terms of Annex I of ANVISA Ordinance No. 354, of August 11th, 2006, republished on the Brazilian Official Gazette of August 21st, 2006, in meeting held on June 14th, 2012, hereby adopts this Resolution and I, Director-President, determine its publication:

Article 1. The Annex of Resolution RDC no. 206, of November 17th, 2006, shall be in force henceforth with the following inclusion and changes:

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“1.12-A – Instructions for use: orientations provided to users by the manufacturer or registration holder for correct product use with safety and efficacy. (New)

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3. Mandatory information on in-vitro diagnostic products. (New Phrasing)

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3.2 Instructions for Use

Instructions for use must be available for users in Portuguese, being allowed to be in non-printed format, as long as they comply with the requirements and conditions established in the specific health legislation." (New Phrasing)

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Article 2. This Resolution shall come into force on the date of its publication.

DIRCEU BRÁS APARECIDO BARBANO