The Collegiate Board of Directors of the Brazilian National Health Surveillance Agency, 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, as well as by Paragraph 1 of Article 111 of the Internal Statute approved by Ordinance no. 593, of August 25th, 2000, in meeting held on February 14th, 2001,

hereby adopts this Resolution and I, Director-President, determine its publication:

Article 1. It is hereby prohibited to import, commercialize and/or receive donations of used healthcare products, defined in the annex hereof, intended for use in the country's health system.

Sole Paragraph. Refurbished healthcare products for which there is no expressive responsibility of the registration holder at Anvisa are hereby included to the aforementioned prohibition.

Article 2. Refurbished healthcare products, defined in the annex hereof, that are imported, commercialized, or received as donations, shall comply with the following requirements:

a) be registered or declared exempt from registration according to the Brazilian sanitary legislation;

b) have the same technical and operational characteristics of the product registered at Anvisa, including labels and instructions for use (manuals) approved upon their registration;

c) have the information that the product is refurbished indelibly affixed to the product, indicating the year the refurbishment thereof was carried out;

d) ensure technical assistance, including the provision of replacement components, parts and pieces during the period addressed in the applicable legislation.

Article 3. Imports of refurbished healthcare products are hereby subject to Anvisa’s approval, provided before their embarkation overseas, and to the submission of the following information:

I. Product identification, including its manufacturer, model, and technical specifications that enable its comparison to the information of the product registered at Anvisa.

II. Statement of the registration holder making the commitment to observe the requirements set forth in Article 2 hereof, according to Normative Instruction no. 1, of December 16th, 1996, issued by the Health Surveillance Secretariat.
Sole Paragraph. The information herein addressed shall be analyzed by Anvisa and the authorization to import the product shall be provided at the location where the product enters national territory (port, international airport, or border office), upon previous health surveillance inspection.

Article 4. Failure to comply with the provisions hereof shall imply partial or total return of the healthcare product at the importer’s expense.

Article 5. This Resolution comes into force on the date of its publication.

GONZALO VECINA NETO

ANNEX

Definitions

**Healthcare product**: medical product, as defined in Law 6,360, of 09/23/1976, and Decree no. 79,094, of 01/05/1977.

**Refurbished healthcare product**: used healthcare product that has been submitted to recycling, refurbishment, revision or reprocessing, or that may include the replacement of components, parts, and pieces, calibration, quality tests, re-sterilization or labeling, among other services required to enable the product to have the same technical and operational conditions provided for its registration at Anvisa, under the registration holder’s expressive responsibility.

**Used healthcare product**: healthcare product that after use has not been submitted to any recycling, refurbishment, revision, or reprocessing process in order to have the technical and operational conditions provided for its registration at Anvisa.