



Cascada de Caño Canoas en la Sierra de la Macarena - Colombia.

MINISTRY OF HEALTH

**NATIONAL INSTITUTE FOR DRUG
AND FOOD SURVEILLANCE - COLOMBIA**



NORA LUCIA RODRIGUEZ

**HEAD OF THE MEDICAL DEVICES AND
HEALTH PRODUCTS COMPLIANCE UNIT**

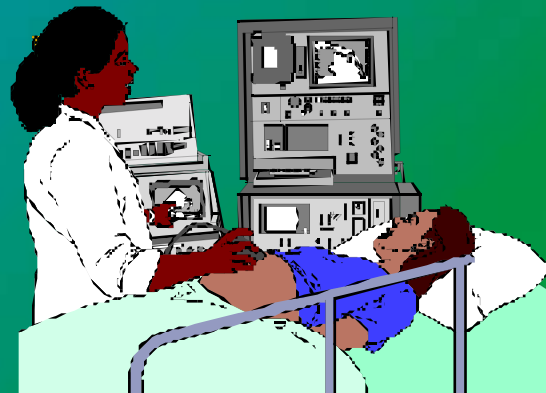
COLOMBIAN REGULATIONS FOR REFURBISHED EQUIPMENT AND MEDICAL DEVICES

SINGAPORE MAY 2002



BIOMEDICAL EQUIPMENT

ANY INSTRUMENT, APPARATUS, EQUIPMENT OR ARTICLE; USED ALONE OR IN COMBINATION INCLUDING COMPONENTS, SPARE PARTS AND SOFTWARE PROGRAMS REQUIRED FOR THE APPROPRIATE OPERATION

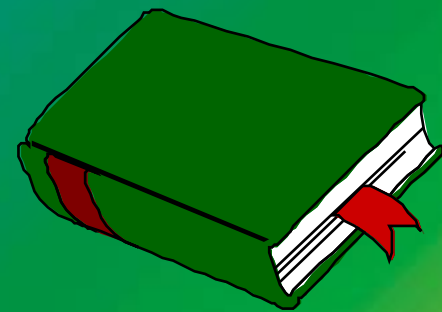




ACTUAL REGULATIONS

RESOLUTION No.434 / 2001

NEW DECREE ON
MEDICAL DEVICES



INVIMA

RESOLUTION 434/2001

CONSIDERATIONS

- DEFINITIONS
- CLASSIFICATION OF BIOMEDICAL EQUIPMENT
- EVALUATION OF THE BIOMEDICAL TECHNOLOGY
- REQUIREMENTS FOR IMPORTATION OR ACQUISITION OF BIOMEDICAL TECHNOLOGY

CLASSIFICATION ACCORDING TO CONDITION

1. **NEW BIOMEDICAL EQUIPMENT**
2. **USED BIOMEDICAL EQUIPMENT:** ALREADY USED OR IN DEMONSTRATION, WITH NO MORE THAN FOUR YEARS OF SERVICE
3. **PROTOTYPES:** EQUIPMENT IN TRIAL PHASE, NOT IN OPERATION.

CLASSIFICATION ACCORDING TO RISK

1. HIGH RISK:

CLASS IIB
CLASS III

INVASIVES
NON INVASIVES
ACTIVES

2. MEDIUM RISK:

CLASS IIA

INVASIVES
NON INVASIVES
ACTIVES

3. LOW RISK:

CLASS I

INVASIVES
NON INVASIVES
ACTIVES

IMPORTATION OR ACQUISITION OF BIOMEDICAL TECHNOLOGY

- **CONTROLLED BIOMEDICAL TECHNOLOGY**

- INCLUDES AN ANNUAL LIST ISSUED BY THE MINISTRY OF HEALTH
- USED OR DONATED MEDICAL EQUIPMENT CLASS I AND CLASS IIA
- PROTOTYPES
HIGH RISK MEDICAL EQUIPMENT CLASS II B AND CLASS III

UNCONTROLLED BIOMEDICAL TECHNOLOGY

INCLUDES CLASS I AND CLASS IIA

🌐 THE IMPORTATION OF BIOMEDICAL
USED EQUIPMENT, BELONGING TO
CLASSES II B OR III ARE PROHIBITED
IN COLOMBIA

CONTROLLED BIOMEDICAL TECHNOLOGY EXAMPLES



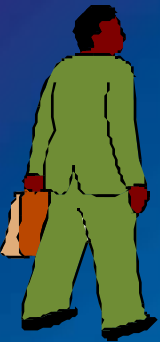
- MRI s
- X RAYS
- C - T
- LAZERS
- GAMMA CAMERAS
- ANGIOGRAPHY SYSTEMS
- HYPERBARIC CAMERAS

TECHNICAL REQUIREMENTS

1. IMPORT REQUEST FORM
2. MANUFACTURER'S CERTIFICATE
3. CHAMBER OF COMMERCE CERTIFICATE
4. QUALITY CONTROL CERTIFICATE ISSUED BY NATIONAL OR INTERNATIONAL ENTITY
5. MANUFACTURER CERTIFICATE OUTLINING:
 - The equipment is not under trial phase
 - Equipment specifications and operation instructions
 - capacity to provide maintenance and support for at least five years
 - training for operators
 - Operating manuals in native language and in Spanish
6. Certificate from the importer indicating the installing, operating and maintaining capacity of the equipment

CONTROL AND SURVEILLANCE

- SUPERINTENDENCY OF NATIONAL HEALTH
- INVIMA
- PROVINCIALS HEALTH AUTHORITIES



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DIFFICULTIES FOR THE BIOMEDICAL EQUIPMENT IMPORTER COMPANIES

- 1. TO MANY STEPS, TO GET THE AUTORIZATION FOR IMPORT (40 DAY APROX.)**
- 2. IMPOSSIBILITY TO IMPORT REMANUFACTURED EQUIPMENT CLASS IIB AND III**
- 3. IMPOSSIBILITY TO IMPORT REFURBISHED SPARE PARTS FOR MORE THAN TWO YEARS OF SERVICE**
- 4. TO IMPORT A SPARE PARTS, IT IS NECESSARY TO FOLLOW ALL PROCEDURES FOR IMPORT A NEW EQUIPMENT**

INVIMA'S WEBSITE

<http://www.invima.gov.co>

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THANK YOU !!!

Laguna del Otún, en el Parque Nacional de los Nevados - Colombia.