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National Drug, Food and Medical Technology

PUBLIC HEALTH

Regulation No. 2319/2002 (3433/2004 layout arranged according to text)

To approve the amended text of "Technical Regulation on Authorization of Company Operation Manufacturer and / or importers of Medical Products." Rectify the Regulation No. 2319/2002.

Buenos Aires, 11/6/2004

SEEN File No. 1-47-2272/04-1 registration of the National Drug, Food and Medical Technology, and

WHEREAS:

That by ANMAT No. 2319/02, he joined the national legal text of Resolution No. 21/98 GMC "Technical Regulation on Authorization of Company Operation Manufacturer and / or importers of Medical Products."

That the Director of Medical Technology informs fs. 1, ANMAT No. 2319/02 was issued by omitting to incorporate the same Annex I and Annex II of Resolution GMC No. 21/98.

That the omission is remedied in terms of what regulated by Article 101 of the Rules of Administrative Procedures approved by Decree No. 1759/72 (TO 1991).

That the Director of Medical Technology and the Directorate of Legal Affairs have taken appropriate action within its competence.

That acting under the powers conferred on

Therefore;

THE AUDITOR OF THE NATIONAL DRUG ADMINISTRATION, FOOD AND MEDICAL TECHNOLOGY ORDERS:

Article 1 - Grinding ANMAT No. 2319 of May 23, 2002, joining the same Annex I and Annex II of Resolution No. 21/98 GMC "Technical Regulation on Authorization of Company Operation Manufacturer and / or Importer Medical Products. "

Article 2 - To approve the amended text of "Technical Regulation on Authorization of Company Operation Manufacturer and / or importers of Medical Products" which was approved by



ANMAT No. 2319/02 as amended by this, which titled "Technical Regulation on Authorization of Company Operation Manufacturer and / or importers of Medical Products. ANMAT No. 2319/02. T.O. 2004," that as part of Annex I to this Order.

Section 3 - Contact the MERCOSUR Administrative Secretariat based in Montevideo, to the knowledge of the States Parties, through the National Section of the Mercosur Common Market Group.

Article 4 - Register, please contact CACID, Cadi, CADIEM, Cadima CAEHFA, fall, CAPA, CAPEMVeL, CAPGEN, CAPROFAC, CILFA, COOPERALA and FAIC. Take to the National Official Register for publication. Give a copy to the Registration Department, the Directorate of Medical Technology and the Department of Institutional Relations. Fulfilled, filed (permanent). - Manuel R. Limeres.

ANNEX I

MERCOSUR / GMC / RES No. 21/98

TECHNICAL REGULATION CONCERNING THE AUTHORIZATION OF OPERATING COMPANY MANUFACTURER AND / OR IMPORTER OF MEDICAL PRODUCTS

SEEN: The Treaty of Asuncion, the Protocol of Ouro Preto, Resolutions No. 91/93, 152/96 Common Market Group and Recommendation No. 1 / 98 WSG No. 11 "Health".

WHEREAS:

That the States Parties approved the contents of the document on the operating license of manufacturer and / or importers of Medical Products.

That there is a need for a single regulation to authorize the operation of companies in each state party.

The Common Market Group

RESOLVED:

Article 1 To approve the Technical Regulations "Operating Authorisation of manufacturers and / or importers of Medical Products" which contains in Annex, versions in Spanish and Portuguese, and part of this resolution.

Article 2 States Parties shall in force the laws, regulations and administrative provisions necessary to comply with this resolution through the following agencies:

ARGENTINA:

Ministry of Health and Social Action

National Drug, Food and Medical Technology



**BRAZIL:**

Health Surveillance Secretariat do Ministério da Saúde

**PARAGUAY:**

Ministry of Public Health and Social Welfare

**URUGUAY:**

Ministry of Public Health

Article 3 States Parties of MERCOSUR should incorporate this resolution to their national laws before 18/1/99.

XXX GMC -Buenos Aires, 22/VII/98

**TECHNICAL REGULATION CONCERNING THE AUTHORIZATION OF OPERATING COMPANY MANUFACTURER AND / OR IMPORTER OF MEDICAL PRODUCTS**

**Part 1**

**Scope**

This regulation applies to all companies that are interested in conducting production and / or import of medical products, with or without commercial purposes in the States Parties.

**Part 2**

**Requirements**

2.1) The applicant must submit to the competent authority, the following documents:

a) Authorisation Application Operating Company whose model is Annex I to this regulation.

b) Request for Registration of Technical Manager of the Company under Annex II of this regulation.

c) Application for inspection for verification of Good Manufacturing Practice for Medicinal Products.

d) Proof of payment of duty on the operating authorization of Company.

e) Plans edilicia distribution, dimensional environments with names that define the destination or use thereof.

f) documentary evidence of the legal constitution of the Company.

g) Copy of document confirming the operating license of the company or evidence of initiation of proceedings against the authority (municipal and / or departmental / provincial). The



requirements for this license are described in the current legislation in the jurisdiction that install the company.

h) Certificate issued by tax authorities.

2.2) The documentation submitted must be original or certified copy.

2.3) Technical responsibility must be exercised by tertiary university-level professionals, trained in the technologies that make medical products marketed by the company, as defined by Resolution MERCOSUR "Registration System of Medical Products."

2.4) Any changes to the data requested in items a, b and e of paragraph 2.1 should be reported to the competent authority, within 30 days.

The Health Authority shall communicate the acceptance or rejection of the amendment within 30 days from receipt of the application, passed the same without representation by the Health Authority, is given as accepted.

### Part 3

#### Grant of Authorization

3.1) The operating permit will be granted once the company has obtained the Certificate of Compliance with Good Manufacturing Practice for Medicinal Products, awarded according to the application referred to in section 2.1.c.

3.2) The authorization to operate the business will be reported in official documents by the Health Authority.

### Part 4

#### Sanctions

4.1) The operating license will be suspended when the company is found default in the performance of point 2.4 of this regulation.

4.2) The authorization for operation of the Company will be canceled if it is proven the falsity of the information in any of the documents referred to in paragraph 2.1 of this regulation.

ANNEX I

## REQUEST FOR AUTHORIZATION OF OPERATING COMPANY

### 1. IDENTIFICATION OF THE COMPANY

#### 1.a. CORPORATE ENTERPRISE

#### 1.b. FULL LEGAL ADDRESS, PHONE, FAX E - MAIL



2. Activities to be undertaken with medical products (manufacture or import, detailing activity):

3. IDENTIFICATION / OF FACILITY / S ENTERPRISE  
COMPLETE ADDRESS, PHONE, FAX OF EACH

4. LEGAL REPRESENTATIVE IDENTIFICATION, SIGNATURE, CLARIFICATION, TYPE AND NUMBER  
OF DOCUMENT

HAVE ENTERED DATA CHARACTER AFFIDAVIT

ANNEX II

REGISTRATION APPLICATION TO ACT AS A RESPONSIBLE TECHNICAL

1. CORPORATE NAME OF COMPANY:

2. IDENTIFICATION OF THE HEAD COACH:

2.a. Full Name:

2.b. PROFESSIONAL TITLE:

2.c. NUMBER OF REGISTRATION / COPY OF CERTIFICATE OF REGISTRATION / REGISTRATION:

2.d. Signature, clarification, TYPE AND NUMBER OF DOCUMENT

HAVE ENTERED DATA CHARACTER AFFIDAVIT

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[http://www.anmat.gov.ar/webanmat/normativa/Normativa/ProductosMedicos/Disposicion\\_A\\_NMAT\\_2319-2002.pdf](http://www.anmat.gov.ar/webanmat/normativa/Normativa/ProductosMedicos/Disposicion_A_NMAT_2319-2002.pdf)

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