RESOLUTION - RE No. 3385, OF OCTOBER 13th, 2006

The Collegiate Board of Directors of the National Health Surveillance Agency, in exercise of the powers vested by the Presidential Decree of July 6th, 2005, and by Anvisa Ordinance no. 368, of August 24th, 2006,

considering the provisions Paragraph 1 of Article 1 of Resolution RDC no. 185, of October 13th, 2006;

considering the need to list the health products whose economic information shall be Submitted;

considering that this matter has been submitted to the Collegiate Board of Directors, which approved it in meeting held on September 26th, 2006, hereby resolves:

Article 1. To establish the attached list of health products whose ECONOMIC INFORMATION REPORT shall be submitted to the Center of Economic Advisement in Regulation upon registration or revalidation submissions.

Article 2. This Resolution shall come into force 60 (sixty) days after its publication.

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ANNEX

1. PRODUCTS FOR CARDIOVASCULAR PROCEDURES

1.1. Implantable cardioverter-defibrillator and cardioverter

1.2. Electrophysiological catheters

1.2.1 Diagnostic purpose

1.2.2 Therapeutic purpose

1.3. Angiographic catheters used in cardiology

1.4. Inducers, sheaths and needles for electrophysiological studies and procedures

1.5. Implantable pacemaker

1.6. Stents
1.6.1 Stents without drugs
1.6.2 Stents with drugs
1.7. Heart Valves
1.8. Vascular endoprosthesis
1.9. Vena cava filter
2. ORTHOPEDIC PRODUCTS
2.1. Anchor mounted with application system
2.2. Orthopedic cements:
   2.2.1 Without drugs
   2.2.2 With drugs
2.3. Spinal Implant:
   2.3.1 Posterior system
   2.3.2 Disc prostheses
   2.3.3 Cage - intervertebral prosthesis
2.4. Bioabsorbable screws for ligamentoplasty
2.5. Total knee prostheses
2.6. Total hip prostheses
2.7. Total shoulder prostheses
2.8. Bone replacement:
   2.8.1 Conductors
   2.8.2 Inducers
3. PRODUCTS FOR CLINICAL ANALYSIS
3.1 Blood glucose analyzer for outpatient and domestic use
3.2 Strips for glucose analyzer for domestic use

3.3 Kits for laboratory diagnosis of:

3.3.1 Hepatitis B

3.3.2 Hepatitis C

3.3.3 HIV

3.3.4 HTLV

3.3.5 Syphilis

3.3.6 Chagas disease

3.3.7 Neonatal Screening:

3.3.7.1 TSH

3.3.7.2 T4

3.3.7.3 Phenylalanine

4. PRODUCTS FOR RENAL REPLACEMENT THERAPY

4.1. Dialyzers

4.2. Equipment for hemodialysis and peritoneal dialysis

5. PRODUCTS FOR OPHTHALMOLOGY

5.1. Intraocular lens

6. PRODUCTS FOR ENT

6.1. Cochlear implants

6.2. Personal Sound Amplification Device

7. PRODUCTS FOR HEMOTHERAPY

7.1. Blood Bags