REGISTRATION AND REGULATORY AFFAIRS DIRECTORATE

GUIDELINES FOR REGISTRATION OF IMPORTED MEDICAL DEVICES IN NIGERIA
NAFDAC/RR/007/00

A. GENERAL

1. These guidelines are for the interest of the general public and in particular medical devices stakeholder in Nigeria.

2. It is necessary to emphasize that, no medical device shall be manufactured, imported, exported, advertised, sold or distributed in Nigeria unless it has been registered in accordance with the provisions of ACT CAP F33 LFN 2004 (Formerly decree 19 of 1993) and the accompanying guidelines.

B. APPLICATIONS/DOCUMENTATION

1. (a) An application for registration of a medical device shall be made by the Manufacturer.

   (b) In case of a manufacturer outside Nigeria such shall be represented in Nigeria by a duly registered company or individual with facilities to effect a recall of the product when necessary.

   (c) An applicant for a manufacturer outside Nigeria must file an evidence of **Power of Attorney** from the manufacturer which authorizes him to speak for his principal on all matters relating to the latter's specialties. The original Power to Attorney is to be notarized and submitted to NAFDAC.

   Or

   Contract Manufacturing Agreement (where applicable). This should be notarized by a notary public in the country of manufacture and submitted to NAFDAC.

   NOTE:
   The representative in Nigeria, whether a corporate body or an individual with the power of attorney, will be held responsible for ensuring that the competent authority in the country is informed of any serious hazard newly associated with a product imported under the provisions of the Act or of any criminal abuse of the certificate in particular to the importation of falsely labeled, spurious, counterfeited or sub-standard medical devices.

   (d) The manufacturer, in the case of imported products, must show evidence that they are licensed to manufacture medical devices for sale in the country of origin (Certificate of Manufacturer and Free Sale). Such evidence must be issued by the Competent Authority of the country of manufacture, and shall be authenticated by the Nigerian Mission in that country. In countries where no Nigerian Embassy or High Commission

exists, any other Embassy or High Commission of any Commonwealth or West African country can authenticate.

2. (a) The applicant shall submit to the office of the Director (Registration and Regulatory Affairs) NAFDAC, a written application, stating name of the manufacturer, generic name (brand name, where applicable) of the products, and obtain the prescribed application form which must be properly filled with all required information.
(b) A separate application form shall be submitted for each regulated product.

3 Evidence of Trade mark approval for brand name from the Federal Ministry of Commerce in Nigeria shall be submitted.

4 Comprehensive Certificate of Analysis of the batch of product to be registered.

5 Certificate of Business Incorporation of the importing company with the Corporate Affairs commission in Nigeria.

C. PRODUCT

1 An applicant shall not be allowed to register a product in more than one brand name, except in cases where the manufacturers are different having different brand names for the same formulation.

D. LABELING

1. Labeling shall be informative, clear and accurate.

2. Minimum requirements on the package label:-
(a) Name of product– brand name (where applicable) must appear in bold letters.
(b) Name and full Location address of the manufacturer.
(c) Provision for NAFDAC Registration Number .
(d) Batch Number, Manufacturing date and Expiry date.
(e) Net contents
(f) Directions for safe use (where necessary) on the information panel (IP) or on the package insert (PI)

3 Any regulated product which is labeled in a foreign language shall **NOT** be considered for registration unless an English translation is included on the label and package insert (where applicable).

E TARIFF

All payments to the Agency shall be in Bank Draft in favour of NATIONAL AGENCY FOR FOOD & DRUG ADMINISTRATION & CONTROL (NAFDAC).

1	Application form	Two hundred and fifty naira (=N=250:00)
2	Per Medical device	=N=250,000:00 + 5% VAT

F NOTE:

1. The registration timeline after submission of samples is eighty (60) work days.
2. Failure to comply with these requirements may result in the disqualification of the application or lead to considerable delay in processing of registration.
3. A successful application attracts a Certificate of Registration with a validity period of 5 (five) years.
4. Registration of a product does not automatically confer Advertising permit. A separate approval by the Agency shall be required if the product is to be advertised.
5. NAFDAC may withdraw the certificate of Registration in the event that the product is advertised without express approval from Agency.
6. NAFDAC reserves the right to revoke, suspend or vary the certificate during its validity period.
7. Filling an application form or paying for an application form does not confer registration status.

All correspondences and applications should be addressed to:

The Director,
Registration & Regulatory Affairs Directorate
National Agency for Food and Drug Administration and Control (NAFDAC)
Central Laboratory Complex
Oshodi, Lagos.
NAFDAC website: www.nafdac.gov.ng
E-mail address: registration@nafdac.gov.ng
Telephone numbers: +234-1-4772452, 01-4772455, 01-4748627