SAMED

advancing patient care through MedTech

Nigeria: Medical Devices & IVDs

February 2022

MEDICAL DEVICES

Medical device" means any instrument, apparatus or contrivance (including components, parts and accessories thereof) manufactured, sold or advertised for internal or external use in the diagnosis, treatment, mitigation or prevention of any disease, disorder, abnormal physical state or the symptom thereof, in man or in animal;

Regulator: SONCAP (Standards Organisation of Nigeria Conformity Assessment Programme)

Process:

Pre-shipment compliance inspection to determine compliance wrt NIS, approved equivalent standards, or technical regulations.

- Uses certified bodies, e.g. Intertek and SGS
- Listed regulated products undergoes conformity assessment in their country of origin
- Registration per product, per manufacturing facility
- Accessories & Parts – listed along with & under main device
- Software products registration not enforced
- Variation/Change required for name or site changes

MEDICAL DEVICES: NAFDAC Process

Regulator: NAFDAC (NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT Cap N.1 LFN 2004

Process:

- Application form to be purchased http://registration.nafdac.gov.ng
- AR required
- Documents (originals + 2 copies) submitted NAFDAC Office complex
- Import permit issued after successful documentation review
- Laboratory Analysis
- Timeline is 120 working days
- Payments made to NAFDAC (~$700 USD)
- License valid for 5 years
- ***NB: Registration does not confer advertising permit***

Requirements:

- Original PoA
- Written Application stating name of the manufacturer of the products
- Trademark Approval
- Quality Certificate
- CFS
- CoA
- Certificate of Business Incorporation
- Label or artwork
- Device label incl. "Provision for NAFDAC Registration Number"
- Letter of Invitation for Good Manufacturing Practice (GMP) Inspection:
- Samples