

TANZANIA FOOD AND DRUGS AUTHORITY



NOTICE TO ALL DEALERS OF MEDICAL DEVICES

COMMENCEMENT OF SECOND PHASE OF REGISTRATION FOR MEDICAL DEVICES FROM JANUARY 2016

1. Tanzania Food and Drugs Authority (TFDA) was established under the Tanzania Food, Drugs and Cosmetics Act, Cap 219 as a regulatory body mandated to control quality, safety and effectiveness of medicines, food, cosmetics and medical devices.
2. Regulation of medical devices involves pre market control through assessment of manufacturer's product information and issuance of registration certificate as an official authorization for the purpose of marketing of products after assessment of safety and performance as provided under Section 51 of the Tanzania Food, Drugs and Cosmetics Act, Cap 219.
3. During the stakeholder's meeting held on 30th March 2015, it was agreed that, the second phase for registration of all medical devices should commence on **1st January 2016**.
4. Implementation of second phase of registration will require that all **medical devices that were not** included in the list for mandatory registration during first phase **in 2009** will require registration.
5. You are therefore reminded to **APPLY** for registration of those products by following requirements provided in the ***Guidelines for Submission of Documentation for Registration of Medical Devices, Edition 1 of 2009***.
6. The applicable fees should be paid through TFDA bank account with the following details:
Tanzania Food and Drugs Authority
Account No. 100380013 USD, Citibank, Tanzania Ltd. Dar es Salaam – Head office Peugeot House, 36 Upanga Road, P. O. Box 71625, Dar es Salaam, Tanzania enter Swift Code: CITITZTZ; or

Local currency: Account No. 6503900110, National Microfinance Bank, Kariakoo Branch OR by banker's draft.
7. It should be noted that, when payment is made by bank transfer all bank charges shall be borne by the applicant who shall also make sure that an advice note is submitted to TFDA giving details of the payment, in particular, the name of the applicant, the device or devices paid for and amount of fees paid.

Issued by:

Director General
Tanzania Food and Drugs Authority (TFDA)
Mandela Road, External Mabibo
P.O. Box 77150, Dar es Salaam
Tel: +255 22 2450 512/2450 751/2452108
Fax: +255 22 2450793
Email: info@tfda.or.tz, website: www.tfda.or.tz

LIST OF MEDICAL DEVICES DURING FIRST PHASE

1. Syringes particularly auto disable
2. Surgical sutures
3. Examination and surgical gloves
4. Scalp vein set
5. Intravenous cannulae
6. Catheters and tubes
7. Contraceptives including condoms
8. Needles
9. Administration Sets (Blood giving and taking sets, blood lancets and I.V giving sets)
10. Blood collection bags
11. Surgical dressing
12. Internal prosthetics replacements
13. Orthopedic implants
14. Bone cements
15. Drug eluting stents
16. Intraocular lenses