



APPLICATION FORM FOR QUALITY AUDIT OF
MEDICAL DEVICES AND DIAGNOSTICS
MANUFACTURING FACILITIES

TMDA/DMC/MDC/F/029

1. PARTICULARS OF APPLICANT/LICENSE HOLDER

Name: _____

Physical Address: _____

Country: _____ Telephone: _____

Fax: _____ E-mail: _____

2. PARTICULARS OF SITE TO BE AUDITED

Name of site: _____

Physical Address (if different from 1. above): _____

Country: _____ Telephone: _____

Fax _____ E-mail: _____

Note: Separate application to be filled in for each individual site

3. CONTACT PERSON ON SITE

Name of contact person: _____

Telephone: _____ Fax: _____

Email: _____



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4. AUTHORISED REPRESENTATIVE/AGENT IN THE COUNTRY

Name of Local Responsible Person: _____

Tel: _____ Email: _____

5. TYPE OF DEVICE

Type of device manufactured (Tick where applicable)

(a) Medical Device (b) IVDD (c) Both (a) and (b)

6. REGISTRATION OF PRODUCTS

Have you registered any medical device in the country: YES NO

Have you submitted dossier for registration? YES NO

If YES, list devices applicable. (Attach a separate sheet if needed): _____

7. APPLICANT DECLARATIONS

I hereby certify that the above information is correct and apply for quality system audit of the above-named site.

Signature of **Applicant and stamp** Date.....

Print Name.....

NOTES:

1. Please submit a hard and soft copy of the Site Master File and Quality Manual together with this



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application.

2. *This application must be submitted together with the appropriate Quality System Audit fee as prescribed in TFDA Fees and Charges Regulations in force.*
3. *As part of device registration process, only applicant who has registered medical devices or submitted dossiers for registration will apply for Quality System Audit. Quality System Audit will not be conducted for facilities which have not submitted device registration dossier(s)*
4. *Devices from manufacturing facilities which are not audited will not be registered or/and deregistered*

9. FOR OFFICIAL USE ONLY

9.1 AUDIT TYPE (Please tick where applicable)

- First Audit
- Re - Audit after failure
- Renewal Audit (Previous audit date
- Other (please specify).....

9.2 OFFICERS ASSIGNED FOR AUDIT)

NO.	NAME OF AUDITOR	SECTION	CONTACT (e-mail & telephone)
1.			
2.			
3.			
4.			