MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

MEDICINES CONTROL COUNCIL

QUESTIONS & ANSWERS:
LICENSING OF MEDICAL DEVICE ESTABLISHMENTS

This document is intended to provide clarity on guidelines and applications for the licensing of medical device establishments. It reflects the current situation and will be regularly updated with changes in legislation and experience gained. It is important that applicants adhere to the administrative requirements to avoid delays in the processing and evaluation of applications.

Guidelines and application forms are available from the office of the Registrar of Medicines and the website.

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REGISTRAR OF MEDICINES

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1 Introduction

The Medicines and Related Substances Act, 1965 (Act 101 of 1965), promulgated on 01 June 2017, makes provision for the implementation of the regulatory oversight of medical devices in South Africa.

This document is a summary of questions that relate to the South African guidelines on the application to licence medical device establishments:

16.03 Guideline for a licence to manufacture, import, export or distribute medical devices and IVDs
16.04 Licence to act as a wholesaler of medical devices and IVDs

and the application forms:

6.21 Licence Application to manufacture, import, distribute or export medical devices
6.22 Licence Application to import, distribute or export medical devices
6.26 Licence Application to Wholesale Medical Devices

and represents the Medicine Control Council's current view.

It is intended to be a dynamic document that supplements and actualizes the above-mentioned documents.

Please visit the MCC website (www.mccza.com) for further information regarding the licensing procedure.

2 Questions about the Submission Requirements

1	**How do I apply for a medical device establishment licence?**
	1.1 Visit the Medicines Control Council (MCC) website at www.mccza.com. 1.2 Click on the tab "Publications" at the top of the page. 1.3 Click on the tab "Application Forms", located second from the top tab on the left of the page. 1.4 Scroll down to the bottom of the page and click on "2" to load the second page of the list of Application Forms. 1.5 Select and download either licence application form: • 6.21 – Manufacturer's Licence; or • 6.22 – Distributor's Licence; or • 6.26 – Wholesaler's Licence 1.6 Complete the relevant application form (in MS Excel format) and submit to the MCC Reception.
2	**What type of licence must I apply for?**
	2.1 There are three different types of medical device establishment licences: • Manufacturer • Distributor • Wholesaler 2.2 The type of licence that you will need will depend on the activities that you are performing. If you are doing any packaging, labelling, servicing or refurbishment of medical devices, you will be required to apply for a Manufacturer's licence. 2.3 If you are doing any distribution activities, such as importation or exportation of medical devices, you will be required to apply for a Distributor's licence. 2.4 If you are doing any wholesaling activities, such as sale, storage, transportation and/or the onward dispatch of medical devices, you will be required to apply for a Wholesaler's licence.

3	**How much does it cost to apply for a medical device establishment licence?**
	3.1 Fees payable are determined in consultation with National Treasury and are published in the *Government Gazette*. 3.2 The following fees, as published in *Government Gazette No. 39154* on 01 September 2015 are currently applicable: • Manufacturer's Licence Fee – R21 000 • Distributor's Licence Fee – R13 000 • Wholesaler's Licence Fee – R13 000 3.3 The fee for a medical device establishment licence application is payable upon application and proof of payment should be submitted together with the completed licence application. 3.4 *Note:* Fees may be updated from time to time. The onus is on the applicant to ensure that payment is made in line with the current fees structures, as published in the *Government Gazette*.
4	**How do I make a payment to the MCC?**
	4.1 Payments to the MCC should be made through electronic funds transfer (EFT). 4.2 The MCC banking details are: Account name: MEDICINES CONTROL COUNCIL Account type: CHEQUE ACCOUNT Account number: 40-5939-2080 Bank: ABSA Bank branch code: 632005 Bank physical address: 240 Madiba Street, Pretoria, 0001, South Africa Swift Code: ABSAZAJJ
5	**Which documents must be submitted when applying for a medical device establishment licence?**
	5.1 All applications should be submitted with a letter of application that has been prepared on a company letterhead, signed by the company director and dated. 5.2 The letter of application must be addressed to the Registrar and marked for the attention of the Medical Device Unit. 5.3 The cover letter must indicate the purpose of the submission, *for example*: • Application for a medical device establishment licence to manufacture, distribute or wholesale medical devices. 5.4 The letter of application must include a list of the attachments that are submitted with the application, f*or example*: • Annex 1: Licence Application • Annex 2: Proof of Payment • Annex 3: Curriculum Vitae of the Authorised Representative • Annex 4: Quality Manual (Manufacturers/Distributors) or • Site Master File (Wholesalers) • Annex 5: CD containing electronic copy of submission *Note:* The CD must meet the CD requirements as indicated on the licence application 5.5 You are required to submit a hard copy (printed copy) of the licence application, initialled by the Authorised Representative on each page, along with the proof of payment of the licence application fee.

	5.6 An electronic version of the completed licence application (in MS Excel format) as well as an electronic copy of the proof of payment must be written/copied onto a CD and provided with the submission of the hard copy. 5.7 The curriculum vitae of the Authorised Representative and the Quality Manual (for Manufacturers and Distributors) or the Site Master File (for Wholesalers) must also be submitted.
6	**When is the deadline to submit a licence application for a medical device establishment?**
	6.1 As per the publication in *Government Gazette No. 40637*, on the 24 February 2017, all unlicensed manufacturers, distributors and wholesalers of medical devices, conducting business in South Africa, at the time of this publication, were required to submit a medical device establishment licence application to the MCC by the 24 August 2017 (for Manufacturers and Distributors) or by the 24 February 2018 (for Wholesalers). 6.2 New medical device establishments wishing to conduct business in South Africa are required to submit a medical device establishment licence application to the MCC prior to commencement of such business. 6.3 Medical device establishments who have not made application for a licence will be considered to be trading in contravention of Section 22C(1)(b) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).
7	**How long does it take to get a licence for a Medical Device Establishment?**
	7.1 Each licence application is evaluated and pronounced upon by the Medical Device Expert Committee. 7.2 The recommendation of the Committee will then be tabled at the MCC for ratification. 7.3 The time lines for licensing are thus dependent on the date of the submission of the application by the applicant and the meeting dates of the Medical Device Expert Committee and the MCC. 7.4 The meeting dates for the Committee and MCC are available on the MCC website.
8	**How do I apply for an amendment to my licence?**
	8.1 A licensee must notify the Registrar in writing of a change to any of the particulars furnished in the application for a medical device establishment licence, which occurs after the issue of the licence. 8.2 The application must be accompanied by the prescribed fee of R2 900, as indicated in *Government Gazette No. 39154* of 01 September 2015, and must contain the following information: • A letter of application indicating the reason for the amendment and describing the proposed changes to be made to the licence; • An electronic copy of the complete licence application (in MS Excel format), containing the updated information; • The registration number of the medical device or IVD (where relevant); • The name and business address of the authorised representative and the holder of a certificate of registration (where relevant); • A declaration by the authorised representative that the information furnished is complete and accurate; • The details of the amendment applied for; • The manufacturer licence number of the manufacturer or the distributor licence number of the distributor; and • Any other information determined by the Authority. *Note:* Fees may be updated from time to time. The onus is on the applicant to ensure that payment is made in line with the current fees structures, as published in the *Government Gazette*.

9	**Must I apply for a licence if I only manufacture / distribute / wholesale Class A devices?**
	9.1 Manufacturers, distributors and wholesalers of Class A devices, which are considered to have a measuring function or which are required to be sterile, must apply for a medical device establishment licence. 9.2 Nothing prohibits manufacturers, distributors and wholesalers of any other Class A devices to apply for a medical device establishment licence.
10	**Who can I contact for assistance with issues pertaining to licensing of Medical Device Establishments?**
	You may contact: Ms Andrea Julsing Keyter E-mail: Andrea.Julsing@health.gov.za Tel: 012 395 9473 Mr Jerry Molokwane E-mail: Jerry.Molokwane@health.gov.za Tel: 012 395 9360

3 Update History

Date	Reason for update	Version & publication
Nov 2017	First publication	v1 Dec 2017