MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

MEDICINES CONTROL COUNCIL

LICENCE APPLICATION TO WHOLESALE MEDICAL DEVICES

- An application form for the purpose of **obtaining** a licence **or renewing** an existing licence in terms of the provisions of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), Section 22C and 22D read together with the regulations relating to medical devices as the case may be.
- This form should be completed by or for each wholesaler of medical devices who wishes to wholesale medical devices or wishes to renew their existing licence.
- A hard copy (printed copy) of the licence application, initialled by the Authorised Representative on each page, as well as an electronic version of the completed licence application (in MS Word format), written/copied onto a compact disc (CD), must be submitted.
- Compact Disc (CD) Requirements:
  - The following statement should be included in the letter of application, after having confirmed that the submission is virus-free: "We confirm that the CD burning session is closed and the submission is checked with an up-to-date and state-of-the art virus checker: *[name of the antivirus software and version of the virus checker]* and is virus-free";
  - CD (CD-ROM) conforming to ISO 9660 or ISO 13346 can be accepted.
  - The use of re-writable disks is not encouraged. When using a re-writable disk, all open sessions must be closed before sending the CD.
  - Each CD should include the following label information, clearly presented and printed on the media:
    - Name of proposed licence holder (Company)
    - The submission date (MM-YYYY)
    - The type of licence applied for
  - The CD should be packed adequately to prevent damage to the media.
- The curriculum vitae of the Authorised Representative and the Site Master File should also be submitted.
- The fee for the application of a licence to wholesale medical devices is payable upon application and proof of payment should be submitted together with the completed licence application. Fees payable are determined in consultation with National Treasury and are published in the *Government Gazette*.
- Payments to the Medicines Control Council (MCC) should be made through electronic funds transfer (EFT).
- The completed form should be sent to:

  The Registrar
  Medicines Control Council
  Private Bag x828
  Pretoria
  0001
- Licensing guidelines are available on the MCC website: www.mccza.com
- The licence is the property of the MCC and must be returned upon demand. The licence remains valid for a period of five years from the date of issue unless suspended or revoked by the MCC.
- After five years, the licence must be renewed on application in the prescribed manner and before the prescribed time, and on payment of the prescribed fee.

Guidance notes for General Information

Wholesaler of Medical Devices

"**wholesaler**" means a dealer who purchases medical devices from a manufacturer or distributor and sells them in terms of section 22H of the Act.

The Wholesaler's Business Name

Full, legal name of licence applicant or owner of the business who wishes to wholesale medical devices. Spaces are provided for the following options. Please insert as applicable.

a) The individual's full name if trading as an individual trader;
b) The name of the registered corporation or company under the Companies Act and **the registration number,** allocated by the Registrar of Companies;
c) The business name, or name under which the business proposes to trade for purposes of the Act [if different from a) or b)].

Authorised Representative

"authorised representative" means a natural person, resident in the Republic of South Africa, who—

a) has the written mandate to represent a manufacturer, distributor or wholesaler in the Republic;
b) acts on behalf of a manufacturer, distributor or wholesaler, for specified tasks with regard to the latter's obligations and in whose name the manufacturer licence, distributor licence, wholesaler licence or certificate of registration is issued; and
c) is responsible for all aspects of the medical device, including performance, quality, safety and compliance with conditions of registration or clinical trials, where relevant.

Declaration

The declaration contained in this application form seeks assurances that the requirements of Section 22C and 22D of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) and regulations 13 and 14 relating to medical devices have been satisfied.

The Authorised Representative appointed and designated by the applicant, to control the wholesaling of medical devices shall be responsible to the MCC for compliance with the Act. The Authorised Representative is responsible for signing the declaration contained in this application form and is responsible for ensuring that the information provided in this application is current and correct at the time it was signed.

Penalties apply for failure to comply with, contravention of the provisions of, or wilfully furnishing of incorrect information in respect of the relevant regulations for medical devices.

Site Information

A Site Master File (SMF) including details of the site, facility, personnel, equipment and quality assurance procedures should be prepared and should be submitted to the MCC, in line with the guidelines on the preparation of a SMF for a Wholesaler of Medical Devices, as determined by the MCC.

Site Inspection

Before a licence may be issued or renewed, the Inspectorate may have to conduct an inspection of the company's wholesaling operations to assess conformity with Good Wholesaling Practice (GWP) as determined by the MCC. The applicant is required to identify an approximate date for an inspection. If this date changes after the application is submitted the Inspectorate should be notified as soon as possible. The inspector assigned to undertake the inspection will advise the wholesaler of the actual date of the inspection approximately five working days beforehand.

Good Wholesaling Practices

The Council may determine written principles to be observed by a wholesaler of medical devices. These principles will primarily comprise of the current guidelines on GWP, available on the MCC website: www.mccza.com.

NOTE: If any of the details contained in this application form should change after this application has been signed and submitted, the applicant will be obliged to submit an updated application form within 30 days. Failure to do so will result in the automatic nullification of the application.

GENERAL INFORMATION

1.1 NAME OF PROPOSED LICENCE HOLDER (COMPANY)

NOTE: A Licence to Wholesale Medical Devices may be granted to either a natural or a legal person.

1.2 LICENCE NUMBER (if known)

2.1 PROPOSED LICENCE HOLDER BUSINESS DETAILS

Name of individual	
Registered company name (if corporation)	
Name (if trading under another business name)	
Company or Corporation Registration number with the Registrar of Companies	

Has this site previously held any licence under the Medicines and Related Substances Act, 1965 (Act 101 of 1965)?	**YES**	**NO**
If YES, please provide details:		

2.2 PROPOSED LICENCE HOLDER ADDRESS FOR COMMUNICATIONS

Town / City	**Postal Code**

3.1 PROPOSED LICENCE HOLDER CONTACT

Surname		**Initials**		**Title**	

Telephone number	
Fax number	
E-mail address	

3.2 Supply details (including licence/permit type, licence/permit number, date of issue of licence/permit) and certified copies of any licence/permit issued by either the Medicines Control Council, the Directorate: Radiation Control or any other regulatory/accredited body.

Licence/Permit Type	
Licence/Permit Number	
Date of issue	
Issued by	

Licence/Permit Type	
Licence/Permit Number	
Date of issue	
Issued by	

Licence/Permit Type	
Licence/Permit Number	
Date of issue	
Issued by	

NOTE: Certified copies of such licences/permits must be attached as annexures to this application form.

SITE INFORMATION

Please complete a separate licence application for each site from which wholesaling (including the sale, storage, transportation and/or the onward dispatch of medical devices) or related activities take place

4.1 SITE NAME

4.2 SITE ADDRESS

Town	**Postal Code**

4.3 SITE TYPE

Is this site used for wholesaling (including the sale, storage, transportation and/or the onward dispatch) of medical devices only?	**YES**	**NO**
Is this site used for other purposes?	**YES**	**NO**
If yes, please specify the other purposes for which the site is used (e.g. order receipt, invoicing, assembly/picking of orders, handling of goods returned from customers, wholesaling of medicines).		
Does the proposed licence holder also hold a Licence to Manufacture Medical Devices for this site?	**YES**	**NO**
Does the proposed licence holder also hold a Licence to Distribute Medical Devices for this site?	**YES**	**NO**
If yes, please indicate the type of licence held by this site and provide the licence number and date of issue:		
Is this site named on any other medical device establishment licence?	**YES**	**NO**
If so please provide the name of the company(ies) and their licence number(s):		

4.4 SITE INFORMATION – SUBMISSION OF SITE MASTER FILE (Tick the appropriate block)

Enclosed ☐ **Submitted before** ☐

Note: Before a licence inspection is conducted wholesalers of medical devices are required to submit a Site Master File including details of the site. Site Master Files previously submitted must not be older than **2 (two) years**.

4.5 SITE MASTER FILE NUMBER (if known)

4.6 CATEGORIES OF MEDICAL DEVICES HANDLED AT THIS SITE

Please indicate by ticking the appropriate box / boxes:

Class Medical Device / **Type Medical Device**		**A**	**B**	**C**	**D**	**RUO**
Measuring Medical Device						
Blood storage / transportation product						
Non-Invasive						
Invasive Medical Device	**< 60 min**					
	>60 min & < 30 days					
	>30 days					
Inactive Medical Device						
Active Medical Device						
Contraceptive						
Combination Medical Device						
IVD						

4.7 SPECIFIC ACTIVITIES

Please indicate by ticking the appropriate box:

Imported medical devices are stored and handled at this site	☐
Locally procured medical devices are stored and handled at this site	☐
"Special" manufactured products are handled at this site	☐
Medical devices are exported from this site on behalf of manufacturers or distributors of medical devices	☐

4.8 METHOD OF ONWARD DISPATCH

Please indicate by ticking the appropriate box:

Post	
Courier/Van service	
Own courier/Van service	
Customer collection	
Other, please specify below:	

4.9 FACILITIES ON SITE

Is the description of the facilities available for the wholesaling of medical devices detailed in the Site Master File?	**YES**	**NO**

If not, please provide a brief description (approximately 500 words), of the facilities available for the wholesaling of medical devices, in an annexure to this application form.

4.10 EQUIPMENT ON SITE

Is a description of the major items of equipment, other than transportation fleets, available for the wholesaling of medical devices detailed in the Site Master File?	**YES**	**NO**

If not, please provide a brief description (approximately 500 words) of the equipment available for the wholesaling of medical devices in an annexure to this application form. In particular please provide details of any refrigeration equipment available.

5 THE AUTHORISED REPRESENTATIVE

Please provide the following details of the Authorised Representative, appointed and designated by the applicant, to control the wholesaling of medical devices, in terms of the provisions of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) and the regulations relating to medical devices.

5.1 Surname | **Name** | **Title**

Business Address

Town	**Postal Code**
Business telephone number	

5.2 Position in Company

5.3 Relevant qualifications

Degree/Diploma	Field of Study	Institution	Year Graduated

5.4 Relevant experience (last job first)

Number of Years	Employer	Position Held

I confirm that the above particulars are, to the best of my knowledge and belief, accurate and true.

I agree to be nominated as the Authorised Representative responsible for wholesale of medical devices as detailed in this licence application.

Signed (Authorised Representative):	Date:

6 PROPOSED DATE FOR INSPECTION

DECLARATION

Applicants should note that in terms of the provisions of the Medicines and Related Substance Act, 1965 (Act 101 of 1965) it is an offence to make false and/or misleading statements in connection with an application for a Licence to Wholesale Medical Devices.

		Tick (✔) one box only in each case	
A.	I declare that:	Yes	No
(i)	The wholesaler had a licence revoked after being granted such a licence.		
(ii)	The wholesaler has been convicted of an offence against the Medicines and Related Substance Act, 1965 (Act 101 of 1965) or a law of a state or territory relating to medical devices.		
(iii)	The wholesaler failed on more than one occasion to observe the wholesale principles in connection with the wholesale of medical devices and IVDs		
(iv)	The information provided in this application is current and correct.		

If parts (i), (ii) or (iii) of the declaration were answered in the affirmative, details should be provided in an annexure to this application form.

B. I apply for the **granting / renewal** (*indicate by crossing out the non-applicable section*) of a Licence to Wholesale Medical Devices, to the proposed licence holder, named in this application form, in respect of the activities to which the application refers.

1. The licence is subject to the requirements of Section 22C and 22D of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) and the relevant regulations relating to medical devices.
2. The activities are conducted only in accordance with the information set out in the application or furnished in connection with it.
3. To the best of my knowledge and belief, the information that the I have provided, in this application form, are correct and complete.

The above declaration must be signed:

- by the Authorised Representative, appointed and designated by the applicant, to control the wholesaling of medical devices, in terms of the provisions of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) and the regulations relating to medical devices.

Name	
Signature	
Position within organisation	
Date	

NOTE: This is a legal document. The MCC must be informed, in writing, by the Authorised Representative, of any changes made to the application, following submission.