Statutory Instrument of 2006.

[CAP. 15:03

Medicines and Allied Substances Control (Gloves) Regulations, 2006

IT is hereby notified that the Minister of Health and Child Welfare has, in terms of section 74 and after consultation with the Authority in terms of section 38, of the Medicines and Allied Substances Control Act *[Chapter 15:03],* made the following regulations:-

Title

1. (1) These regulations may be cited as the Medicines and Allied Substances Control (Gloves) Regulations, 2006.

Interpretation

2. In these regulations -

"form" means the appropriate form set out in the First Schedule;

"glove" means -

(a) a medical glove for single use which is intended for use in the medical field to protect the user from cross-contamination; or
(b) a surgical glove which is sterile, anatomically shaped medical glove with the thump positioned towards the palmar surface of the index finger rather than lying flat, and intended for use in invasive surgery; or
(c) an examination or procedure glove which may or may not be anatomically shaped, intended for conducting medical examinations, diagnostic and therapeutic procedures and for handling contaminated medical materials; or
(d) a seamed or welded medical glove manufactured by welding or otherwise bonding together flat films of material; or
(e) any other glove as determined by the Authority.

Application

3. These regulations shall apply to gloves used or intended for use for any medical purposes.

Sale of unapproved gloves prohibited

4. (1) No person shall sell any gloves unless such glove is of a type which has

been approved by the Authority.

(2) In approving a type of glove in terms of subsection (1) the Authority may fix any conditions it considers necessary or desirable.

Applications for approval of types of gloves

5. Any person who wishes to obtain the approval of the Authority for a type of glove shall apply to the Authority, in duplicate, in Form M.C.G. 1 and such application shall be accompanied by -

(a) the fee specified in section 13; and

(b) the appropriate number of samples as required by the Second Schedule.

Notification of approved types of gloves

6. Where the Authority approves a type of glove the Director-General shall cause to be published in the *Gazette* notification of such approval.

Gloves to meet standards

7. No glove shall be approved by the Authority unless such glove meets the standards as set out in the Second Schedule or as specified by the Authority in guidelines from time to time.

Labelling of gloves

8. Each package of gloves shall state thereon -

(a) the name of manufacturer and place of manufacture; and

(b) the date of manufacture; and

(c) the batch number; and

(d) the date of expiry, if any; and

(e) the size of gloves; and

(f) the methods of sterilization, if any; and

(g) any warnings; and

(h) the type of lubrication; and

(i) the intended use.

Storage of gloves

9. No person who stores for sale any glove shall expose such glove to heat in excess of twenty-eight degrees Celsius, moisture, direct sunlight or fluorescent lighting.

Distribution of unapproved gloves prohibited

10. (1) No importer, manufacturer or wholesaler, as the case may be, shall sell

any glove unless the batch of which such gloves is a part has been approved for distribution by the Authority.

(2) Any person who wishes to obtain the approval of the Authority in terms of subsection (1) shall apply to the Authority, in duplicate, in Form M.C.G. 2.

Notification of change of particulars

11. Every person shall without delay inform the Authority of any alteration from the information or particulars furnished by him in applying for approval for a type of glove in terms of section 5.

Withdrawal of gloves

12. Where the Authority is of the opinion that the withdrawal of any batch of gloves is necessary for the protection of the public, the Authority may require any person to withdraw such batch of gloves in accordance with the procedure as determined by the Authority.

Fees

13. (1) The fee payable in respect of an application for the approval of a type of glove shall be one hundred thousand dollars.

(2) Any costs incurred in testing any gloves for the purpose of obtaining approval in terms of section 4 or subsection (2) of section 10 from the Authority shall be borne by the importer, manufacturer or wholesaler, as the case may be.

Sale of expired gloves prohibited

14. No person shall sell any glove on a date later than the expiry date, which appears on the package of such glove.

Penalties

15. Any person who contravenes these regulations shall be guilty of an offence and liable to a fine not exceeding level seven or to imprisonment for a period not exceeding six months or to both such fine and such imprisonment**.**

FIRST SCHEDULE *(Section 2)*
FORMS

Form M.C.G. 1

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT *[CHAPTER 15:03]*
APPLICATION FOR APPROVAL OF A TYPE OF GLOVE
(To be submitted in duplicate)

Medicines and Allied Substances Control (Gloves) Regulations, 2006
An application in terms of section 5 of the Medicines and Allied Substances Control (Gloves) Regulations, 2006

To be sent to the Director-General, Medicines Control Authority of Zimbabwe, P O Box 10559, Harare, or to be lodged at the offices of the Director-General, Medicines Control Authority of Zimbabwe, 106 Baines Avenue, Harare.

Samples and printed matter to be forwarded by post or other means and carriage, customs duty and clearance to be paid and effected by the applicant in all instances.

1. Particulars of applicant:
   If a sole proprietor: Full names:
   ……
   ……
   If a company: Name of company: …….
   …….
2. Business, Physical and postal addresses:
   ……
   …….
   …….
   …… Telephone number: ……
   Fax number: …… E-mail address……..
3. Registered office …….
4. Name and designation of person completing and signing form ……..…
   ……..
5. Name under which business is conducted ……..
   ……..
6. Name and physical address of manufacturer ……
   ……
7. State whether there may be any alternative places/sources of manufacture other than that referred to in item 6. YES/NO*.
   IF YES, state the name(s) and address(es) of the other manufacturers
   ……..
   ……..

8. Name and address of importer (if different from item 1 or 2) ……
   ……..
9. Name and address of distributor (if different from item 1 or 2) …….
   ……..
10. State trade mark of glove and other distinguishing marks ……
   ……
11. State how glove is packed ……..
   …….
12. State how gloves will be offered for sale in packs or packages to -
   (a) an importer ……
   (b) a wholesaler ……..
   (c) retailer …….
   (d) members of the public ……..

13. State the type of sealing for individual packs of gloves (*e.g. glue, crimping, etc.)* ……
   …….
14. State the specifications of the gloves…… …….
   …….
15. State the specifications of the glove as per Part I of the Second Schedule to the Medicines and Allied Substances Control (Gloves) Regulations, 2006 …….
   …….
16. Give details and explanations of all codes on the packaging which appear on an individual pack of gloves ……..
   …….
17. State number of samples submitted for testing as required by Part II of the Second Schedule to the Medicines and Allied Substances Control (Gloves) Regulations, 2006
   …….
18. I enclose the application fee of …… and undertake to pay the cost for any tests conducted on the gloves and enclose herewith a deposit of …….. towards the cost for testing the gloves.

I, the undersigned, hereby declare that all the information contained herein and in the attachments is correct and true.

Date: ……. …….
Signature of applicant

* ***Delete the inapplicable***

Notes

1. The application fee and any other relevant documents are required to be attached to the application. If the fee or document required to be attached is not attached, the application cannot be accepted.
2. If insufficient space is provided in the application attach a sheet of paper with the additional information.
3. If the form or any part of the form is illegible or not properly completed the application will be rejected.

Form M.C.G. 2

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT *[CHAPTER 15:03]*
APPLICATION FOR TESTING BATCHES OF GLOVES
(To be submitted in duplicate)
Medicines and Allied Substances Control (Gloves) Regulations, 2006

An application in terms of subsection (2) of section 10 of the Medicines and Allied Substances Control (Gloves) Regulations, 2006.

To be sent to the Director-General, Medicines Control Authority of Zimbabwe, P O Box 10559, Harare, or to be lodged at the offices of the Director-General, Medicines Control Authority of Zimbabwe, 106 Baines Avenue, Harare.

Samples and printed matter to be forwarded by post or other means and carriage, customs duty and clearance to be paid and effected by the applicant in all instances.

1. Particulars of applicant:
   If a sole proprietor: Full names:…….
   If a company: Name of company: …….
   …….
2. Business/Physical and postal addresses: ……
   …… Telephone number: ……
   Fax number: …… E-mail address……
3. Registered office ……..
4. Name and designation of person completing and signing form …….
   ……..
5. Name under which business is conducted ……..
   ……..
6. Name and physical address of manufacturer ……
   ……
7. Name and address of importer (if different from item 1 or 2)
   ……..
8. Approval number of type of glove ……..
9. Type of glove ……
10. Batch number to be approved ……
11. Date of manufacture of batch ……
12. I enclose a deposit of …… towards the cost for testing the gloves.

I, the undersigned, hereby declare that all the information contained herein is correct and true.

Date: ……. …….
Signature of applicant

Note:

1. An analyst or an inspector duly authorized by the Authority will visit your premises to obtain random samples from the batch concerned for the purpose of testing them.

SECOND SCHEDULE *(Section 7)*

STANDARDS OF GLOVES

1. SAMPLING AND SELECTION OF TEST PIECES

Gloves shall be sampled and inspected in accordance with ISO 2589-1. The inspection levels and acceptable quality levels (AQLs) shall conform to those specified in Table 1 for the characteristics listed.

When a lot size cannot be determined, a lot of 35 001 to 150 000 shall be assumed.

Table 1 - Inspection Levels and AQLs

Characteristic	**Inspection Level**	**AQL**
Physical dimensions (width, length, thickness	S-2	4,0
Watertightness	S-4	2,5
Tensile strength and elongation at break (before and after accelerated ageing)	S-2	4,0

2. DIMENSIONS

Gloves shall comply with the inspection level and AQL given in Table 1 and the dimensions for palm width and length given in Table 2.

Table 2 - Dimensions and Tolerances

DIMENSION	Size, mm					
	Extra-Small	Small	Medium	Large	Extra-Large	TOLERANCE, MM
Palm Width	70	80	95	110	120	$\pm$ 10
Length	230 all sizes					min.
Thickness at Palm and Finger: Smooth area	For all sizes:- 0.08					min.
textured area	0.11					min.

3. WATERTIGHTNESS

When tested for watertightness, there should be no leakage, using the inspection level and AQL given in Table 1.

Gloves shall be tested by introducing 1 000cm^3 ± 50cm^3 of water at a maximum temperature of 36°C into a holding device designed to hold the glove in a vertical position when filled with water. The glove shall be observed for leakages for 3 minutes.

4. TENSILE PROPERTIES

Requirements on tensile properties for quality control purposes apply to new gloves only. Tensile properties shall be measured in accordance with ISO 37, taking a minimum of three test pieces from each glove and using the median value as the test result. Gloves shall comply with the inspection level and AQL given in Table 1 and the requirements given in Table 3.

Table 3 - Tensile Properties

Property	**Unit**	**Requirement[1]**
Minimum tensile strength before ageing	Mpa	21
Minimum elongation at break before accelerated ageing	%	700
Minimum tensile strength after accelerated ageing	Mpa	16
Minimum elongation at break after accelerated ageing	%	500
[1] If it is necessary for the test piece to be taken from a textured portion, then the requirement shall be 10% lower than those given in this table.		