DRAFT TANZANIA STANDARD

Textiles - Graduated medical compression stockings - Specification

TANZANIA BUREAU OF STANDARDS

Foreword

This Draft Tanzania Standard is being developed by the Hospital Textiles Technical Committee under the supervision of Textile and Leather Divisional Standards Committee and it is in accordance with the procedures of the Bureau.

In the preparation of this standard assistance has been obtained from the following standards:

IS 16467: 2016 Medical Textiles - Graduated medical compression stockings - Specification

In reporting the result of a test or analysis made in accordance with this standard if the final value, calculated or observed is to be rounded off, it shall be done in accordance with TZS 4 *Rounding off numerical values.*

1. Scope

This Draft Tanzania Standard specifies performance requirements, test methods and sampling for graduated medical compression stockings which are designed to exert compression on the legs while standing or walking. It does not apply to support and thrombosis prophylaxis stockings.

2. Normative reference

For the purpose of this Draft Tanzania Standard, the following references shall apply. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies:

TZS 3, *Atmospheric conditions for testing.*

TZS 4, *Rounding off numerical values.*

3. Terms and definitions

For the purpose of this standard, the following terms and definitions shall apply:

3.1 graduated medical compression stockings

stockings which when worn on the leg exert a minimum pressure of 6 mm Hg on the leg surface at the ankle which gets progressively reduced at the calf and the thigh**.**

3.2 compression value

single nominal compression figure characterizing the compression performance of a stocking. It is assigned by the manufacturer based on measurements of similar stockings and is equal to the compression which the stockings are intended to exert at the ankle when worn on a leg of the size designated by the manufacturer.

3.3 compression levels

compression levels at which the stockings are manufactured according to specific medical requirements. The pressure based on the compression levels shall be high at the ankle area and gradually decreases up the garment.

3.4 foot length

horizontal distance between the perpendiculars in contact with the end of the most prominent toe and the most prominent part of the heel, measured with the subject standing and with the weight of the body equally distributed on both feet.

3.5 ankle girth

horizontal girth of human leg just above the medial malleolus, measured with the subject standing and with the weight of the body equally distributed on both feet.

3.6 calf girth

the girth of a human calf measured at its maximum circumference, the upper edge of the tape measure passing horizontally through the point of maximum circumference, measured with the subject standing and with the weight of the body equally distributed on both feet**.**

3.7 thigh girth

horizontal girth of a human leg measured halfway between the crotch and the knee joint, measured with the subject standing and with the weight of the body equally distributed on both feet.

3.8 measuring positions

positions at the ankle, calf and thigh of stockings at which compression is to be measured.

3.9 residual pressure

pressure exerted by the stockings at a point of the leg above the ankle.

4. Materials used

Only materials and dyestuffs that are not harmful to humans are to be used. In particular, these materials must not contain azo dyestuffs that can release carcinogenic amines, allergenic disperse dyestuffs and pesticides. The pH value must be between 5 and 7.

4.1 Textile yarns

Yarns of natural or synthetic fibres can be used.

4.2 Elastic yarns

Yarns made of elastomeric fibres can be used. These yarns must be covered with natural or synthetic fibres.

5. REQUIREMENTS

5.1 Workmanship and Finish

5.1.1 The graduated medical compression stockings shall be clean and free from substances liable to cause tendering during storage. The product shall be free from toxic or harmful substances.

5.1.2 The manufacture and preparation of the graduated medical compression stockings shall be conducted under proper hygienic conditions.

5.2 Size of graduated compression stockings

Sizes of the stocking shall be described in Table 1.

Table 1: Size of compression stocking

S/N	Size	Size at different positions		
		Ankle circumference (cm)	Calf circumference (cm)	Thigh circumference (cm)
1.	S	18-21	28-38	40-60
2.	M	21-26	30-42	46-68
3.	L	26-29	32-46	52-75
4.	XL	29-31	34-50	58-81
5.	XXL	31-35	36-54	64-86

5.3 Performance

5.3.1 *Compression Value*

The manufacturer shall assign a compression value in whole numbers of millimetres of mercury to each stocking based on the measurement of compression in similar stockings. When a sample set of stockings is tested, not more than one stocking of the set shall exert a compression on the ankle outside the range of ± (15 percent + 1 mm Hg) of the claimed compression value.

5.3.2 *Compression Profile*

On any sample of compression stockings, the mean pressure at the three measuring portions shall comply with the requirements given in Table 2.

Table 2: Compression levels

S/N	Compression level	Compression intensity	Compression (kPa)	Compression (mm Hg)
1.	1	Very low	0.8-1.7	6-13
2.	2	Low	Above 1.7-2.4	Above 13-18
3.	3	Moderate	Above 2.4-3.3	Above 18-25
4.	4	High	Above 3.3-5.1	Above 25-38
5.	5	Very high	Above 5.1	Above 38
Note: 1 kPa = 7.5 mm Hg				

5.3.2.1 *Compression levels*

The compression measured in terms of mm Hg refers to the pressure applied at ankle circumference at the smallest girth by compression stockings. The compression levels can be measured using the apparatus described in Annex A.

5.3.3 *Residual pressure ratio*

The residual pressure ratio in percentage of pressure at ankle shall be in accordance with Table 3.

Table 3: Residual pressure ratio in percentage of pressure at ankle

S/N	Compression levels	Residual pressure ration at calf	Residual pressure ration at thigh
1.	1	50-80	20-60
2.	2		20-60
3.	3		20-50
4.	4		20-40
5.	5		20-40

5.4 Durability of compression stockings under repeated washing

After completing 30 washes, in accordance with any wash procedure or with the manufacturer's instruction, each measuring position of the stocking shall retain 85 percent of the compression which it exerted before 30 wash cycles.

6. Packing and marking

6.1 Packing

The graduated medical compression stockings shall be packed securely so as to allow normal handling and transport without tearing and exposing the contents. The details of the packing shall be as agreed to between the buyer and the seller. The packaging of the product should be such as to maintain the integrity of the product throughout its shelf life.

6.2 Marking

Each piece of the graduated medical compression stocking shall be legibly marked with the following information:

a) Name of the product;
b) Product composition
c) Country of origin;
d) Manufacturer's name and site;
e) Date of manufacture and expiry;
f) Size;
g) Compression levels;
h) Direction for use and storage;
i) Batch or lot number;
j) Residual pressure ratio; and

7 Sampling and criteria for conformity

7.1 Lot

All the graduated medical compression stockings of the same material, shape and dimensions produced under similar conditions of manufacture shall constitute a lot.

7.1.1 Each lot shall be tested separately for ascertaining the conformity of the lot.

7.1.2 The number of graduated medical compression stockings to be selected from the lot shall depend on the size of the lot and shall be in accordance with columns 2, 3 and 5 of Table 4.

7.1.3 These graduated medical compression stockings shall be selected at random from the lot.

7.2 Number of tests and criteria for conformity 7.2.1

7.2.1 All the graduated medical compression stockings selected as per col 3 of Table 2 shall be examined for workmanship and finish (see **5.1**).

7.2.1.1 Any graduated medical compression stocking failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as conforming to the above requirements, if the total number of defectives found in the sample is less than or equal to the acceptance number given in col 4 of Table 2. Otherwise, the lot shall be rejected.

7.2.2 Out of the sample already found satisfactory according to **7.2.1.1**, a sub-sample as per column 5 of Table 4 shall be taken. This sub-sample shall be further tested for the remaining requirements.

7.2.3 7.2.3 The lot shall be considered as conforming to the requirements of the specification if the total number of defective stockings found in the sample (as per **7.2.2**) is less than, or equal to the acceptance number as given in column 6 of Table 4.

Table 4: Number of graduated medical compression stockings to be selected

S/N (1)	Lot size (2)	Non-destructive testing		Destructive testing	
		Number of stockings to be selected (3)	Acceptance number (4)	Number of stockings to be selected (5)	Acceptance number (6)
1.	Up to 280	13[1)]	1	8	0
2.	281 to 500	20	2	8	0
3.	501 to 1200	32	3	13	0
4.	1201 to 3200	50	5	13	0
5.	3201 to 10000	80	7	20	1

[1)] or lot size when less than 13.

Annex A
(Clause 5.3.2.1)
COMPRESSION LEVEL MEASUREMENT APPARATUS

A-I PROCEDURE

Five different types of dummy legs each fabricated for the different size of the compression stockings shown in Table I are used. The dummy legs have three grooves marked for placing the sensor. Air sensor are fixed at the three different positions (ankle, calf and thigh) of the dummy leg to measure the compression levels, in mm Hg. The compression stockings are mounted on the dummy leg. The pressure sensed in the compression stockings using the air sensor is converted into numerical value of mm Hg using the following set of connections:

a) Air pump,
b) Air reservoir,
c) SMC sensor,
d) Pressure to voltage adapter,
e) Analog to digital converter, and D PLC.

A-1.1 6 V d.c. Air Pump

A 6 volt de air pump is used for blowing air into the air sensor. The maximum air flow through the sensor is about 70 mm Hg. Hence the air pump is connected with a solenoid, which closes after blowing 70 mm Hg into the air sensor.

A-1.2 Air Reservoir

An air reservoir with a capacity of 0.75 litre is used to compensate fluctuations and act as an accumulator in the event of sudden air consumption.

A-1.3 Digital Sensor

A digital pressure switch is used to transmit the electric pressure signals and also display the pressure instantly. The values are clearly displayed on the LED display screen and different parameters can be had based on data entered from the attached keypad. Hysteresis can be adjusted and unit of measurement of pressure can be modified. The digital sensor pressure value is transmitted to programmable logic controller {PLC) through analog to digital converter (ADC) and the pressure values at each contact point are measured. The PLC monitors and controls the maximum set pressure of 70 mm Hg through the digital sensor.

A-1.4 Pressure to Voltage Adapter

Force sensing resistors which decrease their resistance when a force is applied and convert the resistance into a usable voltage which can be read by the analog to digital converters are used. The same sensor is however used as a closed circuit. The sensing points of the air sensors are in contact as an open circuit (0 V) when the sensing points of the air sensors are open. When the air is filled in the sensors, the sensing point opens and simultaneously the adapter circuit opens. The pressure sensed by the digital sensor at the time of open circuit is transmitted to PLC through the ADC loggers. With the help of ladder logic programmes in the PLC, the pressure value is displayed in the software.

A-1.5 Analog to Digital Converter

This device converts the analog values into digital values and sends them to the PLC. Two ADC data loggers are used, which senses the 3 points in the air sensor and one point from the pressure switch (digital sensor).

A-1.6 PLC

A programmable logic controller (PLC) or programmable controller is a digital computer used for automation of electromechanical process. The force present in the compression stockings are measured using air sensor and adapter board and the analogue signal output from the board is given as input to the PLC's analog extension module. PLC's ladder logic programming is used for the back end process. The PLC converts the AC signal to DC signal and using ladder logic programme, the digital signal is calibrated to the required units.