Israeli Standard – IS 997

October 1988

Amended on….2004

BANDAGES FOR MEDICAL PURPOSES

This standard replaces

Israeli Standard IS-997 of October 1988

Mistake amendment of October 1989

AND INCLUDES

Amendment No. 1 of …… 2004

This document is only a proposal and should not be used as it would be part of, and included in, the Israeli Standard

Cat No 11/15/04

Descriptors: textile products, woven fabrics, cotton, rayon, viscose, medical equipment, gauze, bandages packaging, marking, dimensions, tests.

TABLE OF CONTENTS

In this edition of the standard, changes and amendments were introduced that update the 1988 edition, including the amendment of the mistake therein.
The changes and the additions (amendment No. 1 of 2004) are marked by a frame

In this edition, the heading of the standard was changed.
The former heading of the standard was: Bandages for Medical Purposes: Cotton Bandage and Cotton-Rayon Bandage (Viscose)

CHAPTER A – GENERAL ISSUES

101. VALIDITY OF THE STANDARD [1]

This standard applies to gauze bandages, made of cotton fibre, or of Rayon-Viscose or of a mixture of cotton and Rayon-Viscose fibres, and destined for external medical use as a support to other materials used for bandaging.

102. REFERENCES

Standards and documents referred to in this standard:

Israeli standards

IS 823 part 1 – Fabrics: Standard environments for climate and tests

IS 915 – Medical gauze

Israeli documents

Pharmacists' decree – State of Israel Laws – 1982

Foreign documents

British Pharmacopoeia, 1980

European Pharmacopoeia, latest edition

103. SORTING AND DENOMINATION

Bandages are sorted and denominated as follows:

103.1 Materials they are made of

103.1.1. Gauze bandage made from cotton;

103.1.2. Gauze bandage made from Rayon-Viscose

103.1.3. Gauze bandage made from cotton and Rayon-Viscose

103.2 Number of fibres per cm. in the woven (wrap & woof = W&W) pattern;

103.1.4. W&W 18;

103.1.5. W&W 20;

103.1.6. W&W 24;

[1] According to Pharmacists' Decree in our possession for the State of Israel (New version 1982) Validity on Medical Products Requirements of the Official Pharmacopoeia, as its implication in paragraph 44 of the Decree, but if the manager decided otherwise, the requirements in this standard are in accordance with the requirements of the Official Pharmacopoeia, however, it includes additional requirements.

103.1.7. W&W 27;

104. PACKAGING

104.1 Packaging Unit

Bandages sold as single unit will be packed in such a way that will protect it from humidity, dirt and dust.

104.2 Bulk Packaging

Bandages sold in bulk packaging (containing more than one bandage); each of them will be wrapped in such a way that their rolled shape will be preserved. The bulk packaging will preserve the bandages from humidity, dirt and dust.

105. MARKING

105.1 Packaging Unit

Each packaging unit will be marked using a clear and permanent marking that will include the following items:

105.1.1. Manufacturer's name and address;

105.1.2. The words "Gauze bandage" and bandage type according to paragraph 103;

105.1.3. Dimensions: Width (cm.), Length (m.);

105.1.4. Batch identification mark and manufacturing date;

105.1.5. Importer's name and address;

105.1.6. Country of manufacture.

105.2 Bulk Packaging

Bulk packaging will be marked, in addition to the items mentioned above, with the following items:

105.2.1 Number of bandages contained;

105.2.2 The words: "Destined for external use but not for application on wound" – The words will be written in a script using clearly visible text. Bandages to be sold in Israel will be marked in the Hebrew language. Translation into a different languages is allowed, provided that it will not be more noticeable than the Hebrew text.
If the bandage dimensions are in inches or yards, the metric dimensions will be added correspondingly.

106. COMPLIANCE WITH THE STANDARD

106.1 Compliance of a Batch of Bandages with the Standard

In order to state that a batch of bandages of a uniform type, manufactured by a single manufacturer in uniform conditions, complies with the standard, the following procedure is performed:
A random sample, whose size is described in Table 1, is selected from the batch.

Table 1

Number of Bandages in Batch	Sample Size	Acceptance No.
Up to 500	2	0
501 and more	8	1

From each bandage of the sample a single piece is cut–off along the entire width of the bandage, in such a way that its size will be large enough to perform the tests. If a little of the bandage is cut-off, the cut is made at 10% of the entire length of the bandage. The batch complies with the standard, if the number of defective bandages of the sample that did not meet all the requirements of the standard or part of them, is not greater than the acceptance number indicated in Table 1.

106.2 Compliance of one Bandage with the Standard

In order to determine if one bandage complies with the standard, it is tested for compliance to all the requirements of the standard.
The bandage complies with the standard if it complies with all its requirements.
The bandage does not comply with the standard, if it does not comply with any one requirement, even if it is one of the bandages of the batch of bandages found complying with the standard according to paragraph 106.1.

CHAPTER B – REQUIREMENTS

201. GENERAL REQUIREMENTS

Bandages of type 103.1.1 will be gauze bandages made of cotton that has been bleached or dyed a colour other than white.

The gauze will not undergo optical bleaching.

Bandages of type 103.1.1 will be gauze bandages made of cotton that has been bleached by non – optical bleaching and Rayon-Viscose fibre.

Bandages will be manufactured in hygienic conditions, according to the specifications of the Ministry of Health.

Bandages without fringes will be cut following a straight line and parallel to the wrap fibres. The bandage will be of one piece and rolled in a tight roll. It will not have any loose fibres that would interfere with fasciations.

Bandages will be free of stains or defects that would reduce its serviceability.

202. DIMENSIONS

To be measured as indicated in paragraph 303.

202.1 Length

The length of the bandage will be one of the following with an allowed deviation of -1%:
2.70 m.; 3.60 m.; 4.00 m.; 5.00 m.

202.2 Width

The width of the bandage will be one of the widths described in table 2

Table 2

Bandage width [cm.]	3.5	4.0	5.0	6.0	7.0	8.0	10.0	12.0	15.0	20.0

Tolerance	+ 0.3 - 0.2	+ 0.4 - 0.2	+0.5 - 0.3	+0.6 - 0.4

203. BANDAGE CHARACTERISTICS

In the tests described in Table 3 bandage characteristics will be as detailed in the table

Table 3

Serial No.	Bandage Characteristics	The requirement				Test After
		W&W 18	**W&W 20**	**W&W 24**	**W&W 27**	
1	Number of fibres in 10 cm. in wrap min. - bandage with fringes	100 ± 5	120 ± 6	120 ± 6	140 ± 7	Para. 304
	- bandage without fringes.	97	117	117	136	
2	Number of fibres in 10 cm. in woof	80 ± 5	80 ± 5	120 ± 6	130 ± 7	
3	Load per unit of area (gr/m^2) min. - bandage with fringes	24	27	32	36	Para. 305
	- bandage without fringes	29	31.5	36	40	
4	Tension strength in the wrap direction (Newton) min. Of bandage type 103.1.2	50	60	60	67	IS 915 A
4a	Tension strength in wet condition in the wrap direction (Newton) min. Of bandage type 103.1.2	50	60	60	67	Para. 306
5	pH	4.5 - 8				IS 915
6	Absorption ability: sedimentation time (seconds), max.	10				
7	Ash contents (percentage of 100 of dry weight), max.	Type 103.1.1 : 0.4 Type 103.1.2 : 1.2 Type 103.1.3 : 1.2				
8	Fluorides	Random spots only				
9	Whiteness (percentage of 100) min.	70 (for white products)				

(Table continued on next page)

Table 3 (continued)

Serial No.	Bandage Characteristics	The Requirement	Test After
10	Exhaustion residues in water (percentage of dry weight) max.	Type 103.1.1 : 0.5 Type 103.1.2 : 0.7 Type 103.1.3 : 0.7	IS 915
11	Exhaustion residues in water (percentage of dry weight) max.	0.5	
		No reddish, violet or brown colour will show	
	Humidity content (%) max.	Type 103.1.1 : 8 Type 103.1.2 : 11 Type 103.1.3 : 11	

Remarks to the table:

(a) Bandages of 103.1.2 type are tested as required by IS 915 with the following change: Required strip is cut according to IS 915 (at least twice the length required by IS 915). Each strip is cut along its width into two parts: one to determine the value of the tensile strength in dry conditions, and the other to determine the value of the tensile strength in wet conditions. (This ensures that each of the parts have the same number of fibres in the wrap direction).

(b) This characteristic is tested only for type 103.1.2 – Gauze bandages made from Rayon-Viscose. The remaining types are not tested by this procedure.

204. OVERALL COUNT OF MICRO-ORGANISMS

The bandage is tested as described in European Pharmacopoeia, updated edition.

The number of micro-organisms as described in European Pharmacopoeia, updated edition, for products destined for application to skin.

Chapter C – Test Methods

301. TEST CONDITIONS

All tests on the bandage, except visual tests, will be performed in climatic conditions as described in the Israeli Standard IS 823 - part 1. All tests on the gauze that the bandage is made from, that are not described in this standard, will be performed by methods as described in the Israeli Standard IS 915.

302. MATERIAL IDENTIFICATION

The materials the bandage is made from will be tested by their mutual rate including weight, by one of the methods described in the British Pharmacopoeia of 1980 (SMDI method).

303. DIMENSIONS TEST

The bandage is unfolded and is straightened without tension. The width and length of the bandage are measured using a divided rule, which enables 1 mm. measuring precision. The width of the bandage is measured at various locations (at least 5 locations) and the average is stated.

304. NUMBER OF FIBRES TEST

Five samples are cut-off for testing. When the width of the bandage exceeds 10 cm. square samples of 10 cm. sides are cut.
All wrap and woof fibres of the tested sample are counted. The average number of fibres is calculated out of 5 samples of 10 cm. in wrap and 10 cm. in woof.

305. DISOLUTION TEST PER AREA UNIT

Five samples at least, with a total area of about 500 cm^2 are cut from different places on the bandage.
When the samples are cut from the edge of the bandage, the first cut should be away from the end of the bandage at about 10% of its overall length.
The samples will be weighed using scales with a precision of 0.01 gr. and the mass of 1 mm^2 is calculated.

306. TENSION STRENGTH IN WET CONDITIONS IN THE WRAP DIRECTION OF A GAUZE BANDAGE MADE OF RAYON-VISCOSE (TYPE 103.1.2)

Tension strength testing under wet conditions in the wrap direction is tested as described in the Israeli Standard IS 915 in the paragraph that deals with the tension, with the following additions:
The samples are laid on a surface of distilled water or water free of ions at a temperature of 17ºC to 30ºC until they will sink by themselves, however if the time required for them to sink is longer than 2 hours, they should be forced to sink for an additional hour, at least.
If it becomes necessary to impregnate the samples, full impregnation of those that are generally immune to impregnation, the use of a watery solution that contains non ionic moisturizing material in an amount not exceeding 1 gr./litre instead of water is permitted.

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