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Foreword

This European Standard has been prepared by Technical Committee TC 205 'Non-active medical devices' of which the secretariat is held by BSI.

This European Standard has been prepared under a Mandate given to CEN by the Commission of the European Communities and the European Free Trade Association, and supports essential requirements of EC Directive(s).

This European Standard was approved on 19XX-XX-XX and, in accordance with the CEN/CENELEC Internal Regulations, the following countries are bound to implement this European Standard:

Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

The following dates have been fixed

| | |
|--|------------|
| - Latest date of announcement of the EN at national level (doa) | 19XX-XX-XX |
| - Latest date of publication of an identical national standard (dop) | 19XX-XX-XX |
| - Latest date of withdrawal of conflicting national standards (dow) | 19XX-XX-XX |

Annexes B and C are normative and form part of this European Standard. Annexes A and D are for information only.

For relationship with EU Directive, see informative Annex E, which is an integral part of this standard.

0 Introduction

An important property of hosiery is its durability, i.e. the retention of its designed compression during its lifetime. Hitherto the durability of hosiery has been achieved by the choice of the materials of construction and the methods by which hosiery has been manufactured. Experience has shown that hosiery having appropriate medical characteristics can be produced by paying due regard to information in annex A. A method of testing durability is under development in CEN/TC 205 and, together with requirements for durability, is intended to form a future Part of this European Standard and to supersede annex A.

1 Scope

This European Standard specifies requirements and performance and gives test methods for medical compression hosiery, including custom-made hosiery, knitted from threads made of natural fibres or synthetic fibres and elastic threads. It is applicable to medical compression hosiery which is used as a medical device for the treatment of venous and/or lymphatic diseases of the leg.

NOTE: This European Standard does not give requirements connected with the manufacture of hosiery. Manufacturing methods that have been shown by experience to be satisfactory are given for information in annex A. A method of testing the durability of hosiery is under development in CEN/TC 205 and, together with durability requirements, is intended to form a future Part of this European Standard, and will supersede annex A.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

- EN 45001: 19.. General criteria for the operation of testing laboratories
- ISO 139: 1973 Textiles - Standard atmospheres for conditioning and testing
- ISO 376: 1987 Metallic materials - Calibration of force-proving instruments used for the verification of uniaxial testing machines
- ISO 1144: 1973 Textiles - Universal system for designating linear density (Tex System)
- ISO 2321: 1983 Rubber threads - Methods of test
- ISO 3758: 1991 Textiles - Care labelling code using symbols
- ISO 6330: 1984 Textiles - Domestic washing and drying procedures for textile testing

3 Definitions

For the purposes of this standard, the following definitions apply:

3.1 compression: Pressure exerted on the leg by the hosiery.

3.2 compression classes: Compression grades in which hosiery is produced, categorised by the compression at the ankle.

3.3 unit of thread thickness (conventional count of a rubber thread; gauge number round (not square): The number of threads which, when placed side by side, measure 25,4 mm.

3.4 custom made hosiery: Hosiery manufactured individually to suit the leg dimensions of an individual patient.

3.5 durability: Ability of hosiery to retain its designed compression after a procedure that simulates repeated washing and wearing.

3.6 elastic material: Material which increases its dimension under the action of an applied force and returns to almost its original form when the force is removed.

3.7 extensibility: Maximum degree, expressed as a percentage of the unloaded size of the hosiery, in which the hosiery can be stretched in the circumferential or in the longitudinal direction under the test procedure specified in this European Standard.

3.8 inlaid thread: Elastic thread which does not form stitches or loops and which is inlaid in the direction of the course.

3.9 medical compression hosiery: Hosiery for treating leg diseases by means of graduated compression exerting a definite pressure on the leg in a specific way.

NOTE - Abbreviated in this standard to 'hosiery'.

3.10 practical elongation: Elongation of hosiery in the circumferential direction with the hosiery on the leg, expressed as a percentage of the unloaded circumference of the hosiery.

3.11 pressure profile: Representation of the compression exerted by the hosiery along the leg.

3.12 residual pressure: Compression at a certain point expressed as a percentage of the compression at the ankle.

3.13 stiffness: Increase in compression per centimetre increase in the circumference of the leg, expressed in hectopascals per centimetre and/or millimetres of mercury per centimetre.

3.14 standard size hosiery: Hosiery manufactured in the types and sizes specified in this European Standard.

3.15 tolerance of standard size hosiery: Limits of the girth and length of the leg between which the standard size hosiery is intended to be used.

3.16 unit of linear density: Mass in decigrams of 1 km of yarn expressed in dtex.

NOTE: The basic unit is the tex.

4 Compression classes

Hosiery shall be classified into four compression classes as shown in table 1, and the compression shall be measured in accordance with annex B.

Table 1: Compression classes

| Compression class | Compression at the ankle ¹⁾ | |
|--------------------|--|---------------------|
| | hPa | mm Hg ²⁾ |
| Ccl I mild | 20 to 28 | 15 to 21 |
| Ccl II moderate | 31 to 43 | 23 to 32 |
| Ccl III strong | 45 to 61 | 34 to 46 |
| Ccl IV very strong | 65 and higher | 49 and higher |

¹⁾ The values indicate the compression exerted by the hosiery at a hypothetical cylindrical ankle.

²⁾ 1 mm Hg = 133,3 Pa.

NOTE: The package can be labeled as follows:
- 15 - 17 mm: Class 1.A;
- 18 - 21 mm: Class 1 B.

5 Dimensions and standard sizes

5.1 General

Hosiery size shall be designated by the lengths and girths on the human leg at the measuring points given in table 2 and figure 1.

5.2 Measurement of length

Length shall be measured and codes allocated in accordance with table 3.

5.3 Measurement of girth

Girths shall be measured and codes allocated in accordance with table 4.

5.4 Sizes

NOTE: In order to facilitate the use of hosiery and to give a unique basis for the test methods specified in this European Standard, this system of sizes is specified based on the ankle girth.

5.4.1 Length

Lengths shall be chosen from table 5.

5.4.2 Girth

Girths shall be chosen from table 6.

5.5 Designation of type of hosiery

The type of hosiery shall be designated by the code in accordance with table 7.

5.6 Designation of type and size of hosiery

Hosiery shall be designated by the type code according to table 7 followed by three pairs of numbers indicating the dimensions of the legs that the hosiery is intended to fit as follows:

- the range of girth at the ankle according to table 6;
- the range of girth at the upper end of the hosiery according to table 6;
- the range of length according to table 5.

NOTE: An example of type and size designation is AD (22-24/34-36) - (42-45)

where

AD is the code for below-knee hosiery;

22-24 is the range of girth at the ankle (22 cm to 24 cm);

34-36 is the range of girth at the upper end of the hosiery (34 cm to 36 cm);

42-45 is the range of length (LD) (42 cm to 45 cm).

NOTE: Measurements should preferably be taken with the leg in the standing position.

Figure 1: Measuring points, lengths and girths on the human leg (see table 2)

Table 2: Measuring points (see figure 1)

| Measuring point | Description of the measuring point |
|-----------------|--|
| <i>a</i> | sole of the foot at the heel |
| <i>A</i> | forefoot at the implantation of the toes |
| <i>B</i> | ankle at the point of its minimum girth |
| <i>B1</i> | point at which the achilles tendon changes into the calf muscles |
| <i>C</i> | calf at its maximum girth |
| <i>D</i> | just below the tibial tuberosity |
| <i>E</i> | centre of the patella and over the back of the knee |
| <i>F</i> | between <i>K</i> and <i>E</i> |
| <i>G</i> | 5 cm below <i>K</i> with the patient in the upright position |
| <i>H</i> | greatest lateral trochanteric projections of the buttock |
| <i>K</i> | centre point of the crutch |
| <i>K1</i> | level at the pubic symphis |
| <i>K2</i> | level at the infra gluteul-fold |
| <i>T</i> | natural waistline |
| <i>X</i> | middle of the foot |
| <i>Y</i> | instep |
| <i>Z</i> | tip of toe |

Table 3: Measurement of length

| Length code | Length of the leg |
|---|--|
| <i>IB</i> | distance measured from <i>a</i> to <i>B</i> |
| <i>IBI</i> | distance measured from <i>a</i> to <i>BI</i> |
| <i>IC</i> | distance measured from <i>a</i> to <i>C</i> |
| <i>ID</i> | distance measured from <i>a</i> to <i>D</i> |
| <i>IE</i> | distance measured from <i>a</i> to <i>E</i> |
| <i>IF</i> | distance measured from <i>a</i> to <i>F</i> |
| <i>IG</i> | distance measured from <i>a</i> to <i>G</i> |
| <i>IH</i> | distance measured from <i>a</i> to <i>H</i> |
| <i>IK</i> | distance measured from <i>a</i> to <i>K</i> |
| <i>IT</i> | distance measured from <i>a</i> to <i>T</i> |
| <i>IX</i> | distance measured from the most prominent part of the heel to <i>X</i> |
| <i>IA</i> | distance measured from the most prominent part of the heel to <i>A</i> (foot length without toe) |
| <i>IZ</i> | horizontal distance between the perpendiculars in contact with the end of the most prominent toe and the most prominent part of the heel (total foot length) |
| <i>IGT</i> ¹⁾ | distance measured from <i>G</i> to <i>T</i> |
| <i>IK1T</i> ¹⁾ | distance measured from <i>K1</i> to <i>T</i> |
| <i>IK2T</i> ¹⁾ | distance measured from <i>K2</i> to <i>T</i> |
| ¹⁾ For panty hose only, measured along the body. | |

Table 4: Measurement of girth

| Girth code | Girth of the leg |
|------------|--|
| <i>cA</i> | girth measured at <i>A</i> |
| <i>cB</i> | girth measured at <i>B</i> |
| <i>cB1</i> | girth measured at <i>B1</i> |
| <i>cC</i> | girth measured at <i>C</i> |
| <i>cD</i> | girth measured at <i>D</i> |
| <i>cE</i> | girth measured at <i>E</i> |
| <i>cF</i> | girth measured at <i>F</i> |
| <i>cG</i> | girth measured at <i>G</i> |
| <i>cH</i> | girth measured at <i>H</i> |
| <i>cT</i> | girth measured at <i>T</i> |
| <i>cX</i> | girth measured at <i>X</i> |
| <i>cY</i> | girth at <i>Y</i> , measured with the foot in maximum dorsal flexion |

Table 5: Leg lengths for standard size hosiery

| Length code | Length cm | | |
|-------------|---------------|----------------|--------------|
| | short hosiery | normal hosiery | long hosiery |
| <i>IG</i> | 68 | 74 | 80 |
| <i>IF</i> | 57 | 62 | 67 |
| <i>IE</i> | 43 | 47 | 51 |
| <i>ID</i> | 37 | 40 | 43 |
| <i>IC</i> | 29 | 32 | 35 |
| <i>IB1</i> | 20 | 22 | 24 |
| <i>IB</i> | 11 | 12 | 13 |

Table 6: Leg girths¹⁾

| | | Dimensions in centimetres | | | | | | | | | | | | | | | | | | |
|------------|--------------------|---------------------------|----|----|----|----|----|----|----|----|----|----|-------------------|----|----|----|--|--|--|--|
| Girth code | Slender supplement | Size of hosiery | | | | | | | | | | | | | | | | | | |
| | | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | Sturdy supplement | | | | | | | |
| cG | 48 49 51 | 52 | 54 | 55 | 57 | 58 | 60 | 61 | 63 | 64 | 66 | 67 | 69 | 70 | 72 | 73 | | | | |
| cF | 40 41 43 | 44 | 46 | 47 | 49 | 50 | 52 | 53 | 55 | 56 | 58 | 59 | 60 | 61 | 62 | 63 | | | | |
| cE | 33 34 35 | 36 | 37 | 38 | 39 | 40 | 41 | 42 | 43 | 44 | 45 | 46 | 47 | 48 | 49 | 50 | | | | |
| cD | 28 29 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 | 42 | 43 | 44 | 45 | | | | |
| cC | - 30 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 | 42 | 43 | 44 | - | - | | | | |
| cB1 | - 23 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | - | - | | | | |
| cB | - - - | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | - | - | - | - | | | | |
| cY | - - - | 29 | 30 | 31 | 32 | 32 | 33 | 34 | 34 | 35 | 35 | 36 | - | - | - | - | | | | |

¹⁾ Range of leg girths can be chosen from this table.

Table 7: Designation of types of hosiery

| Type of hosiery | Code |
|---|---------------------------|
| Below-knee hosiery | AD |
| Mid-thigh hosiery | AF |
| Thigh hosiery | AG |
| Single leg panty | AGTL ¹⁾ , AGTR |
| Panty hosiery | AT |
| ¹⁾ L = left leg; R = right leg | |

6 Heel

Hosiery shall possess a closed and knitted heel with the appropriate anatomic form and stretch qualities. If the hosiery is of the type described in A.8.1 b), it shall be knitted with a reciprocated heel.

Testing shall be carried out by visual inspection.

NOTE: It is expected that this requirement will be revised when a measuring method for heel pressure is available.

7 Seams

Seams shall be smooth on the inside of the hosiery.

NOTE: Seams may be overlapped.

Testing shall be carried out by visual inspection.

8 Edges

Edges shall be non-fray.

Testing shall be carried out by visual inspection.

9 Shaping and forming

The compression profile shall be achieved by knitting and not by shaping or forming.

NOTE: There may be boarding for presentation.

10 Mechanical properties

10.1 Extensibility

Hosiery shall be capable of being stretched at least 120 % in the circumferential direction at all measuring points specified in 5.3. The stretch capability in the longitudinal direction shall be at least 30 % at all measuring points specified in 5.2.

Testing shall be carried out in accordance with annex C.

10.2 Practical elongation

The practical elongation shall be not less than 15 % and not more than 140 % at all measuring points specified in 5.3.

Testing shall be carried out at measuring points *B* and *C* and *F* and *G*, where applicable, in accordance with annex B.

10.3 Residual pressure

The residual pressure of the hosiery shall lie within the area determined by the residual pressure as given in table 8 at the *B1*, *C*, *F* and *G* measuring points where applicable.

The residual pressure shall at no measuring point along the leg, except *E*, be of a higher value than the residual pressure at the measuring point situated distally. The pressure profile along the leg shall conform to the values given in table 8.

NOTE: The residual pressure may be lower at the *E*-level, than that which follows from the interpolation of the values *D* and *F*.

In order to avoid irregularities of the pressure profile along the leg, the residual pressure shall be measured at measuring points *B*, *B1*, *C*, *D*, *E*, *F* and *G*, where applicable.

Testing shall be carried out in accordance with annex B.

10.4 Durability of compression

NOTE 1: Hosiery should last approximately 6 months in normal use. Hosiery manufacturing methods are given in annex A.

NOTE 2: This recommendation will be replaced when a durability test has been agreed.

Table 8: Ranges of pressure profiles

| Compression Class | % of compression exerted at ankle | | |
|-------------------|-----------------------------------|-------------|-------------------------|
| | at <i>B1</i> | at <i>C</i> | at <i>F</i> or <i>G</i> |
| Ccl I | 80 to 100 | 60 to 80 | 30 to 60 |
| Ccl II | 80 to 100 | 60 to 80 | 20 to 50 |

| | | | |
|---------|-----------|----------|----------|
| Ccl III | 80 to 100 | 50 to 70 | 20 to 40 |
| Ccl IV | 80 to 100 | 50 to 70 | 20 to 40 |

11 Packaging

Hosiery shall be packaged so that exposure of the hosiery to sunlight is minimized.

12 Marking

12.1 Marking of hosiery

Hosiery shall be marked at least with the following information:

- a) name or trade name of the manufacturer or distributor;
- b) name of the product;
- c) fibre content (unless marked on the package);
- d) compression class;
- e) either the type and size indication as specified in 5.6 or a statement that the hosiery is custom made;
- f) washing and treatment symbols in accordance with ISO 3758.

12.2 Marking of the package

The package shall be marked at least with the following information:

- a) name and address of the manufacturer or distributor;
- b) name of the product;
- c) country of origin if manufactured outside the European Economic Community;
- d) fibre content (unless marked on the hosiery);
- e) compression class;
- f) type and size indication as specified in 5.6 or a statement that the hosiery is custom made;

NOTE: The following information may also be given.

- g) stiffness;
- h) diagrammatic representation of the range of leg sizes that the hosiery is intended to fit.

12.3 Instructions for use

The package or a leaflet in the package shall contain the following information:

- a) instructions for washing;
- b) instructions for use and warnings about misuse;

NOTE - The following information may also be given

- c) diagrammatic representation of the range of leg sizes that the hosiery is intended to fit.

Annex A (informative)

Hosiery manufacturing methods

A.1 Introduction

An important property of hosiery is the retention of its designed compression during its lifetime. A method of testing this property, known as 'durability', is under development in CEN/TC 205 and, together with requirements for durability, is intended to form a future Part of this European Standard, and will supersede annex A.

Hitherto the durability of hosiery has been achieved by the choice of the materials of construction and the methods by which hosiery has been manufactured. Experience has shown that hosiery having appropriate medical characteristics can be produced by paying due regard to the following.

A.2 Threads

Textile threads made of natural or synthetic fibres and elastic threads made of elastodiene or elastane should be used. A method of test for the analysis of elastic threads is given in A.3.

A.3 Method of analysis of elastic threads in hosiery

A.3.1 Principle

Chemical identification of elastic materials in hosiery.

A.3.2 Apparatus and reagents

A.3.2.1 Microscope.

A.3.2.2 Acetic acid solution, 98 % V/V in water.

A.3.2.3 Formic acid solution, 85 % V/V in water.

A.3.3 Test procedure

Mix three parts of acetic acid solution (A.3.2.2) and one part of formic acid solution (A.3.2.3).

Place the test sample on a microscope slide. Moisten it with the mixture of acids and observe it under the microscope (A.3.2.1).

If the test sample starts to swell, the thread is elastane. If there is no change in the test piece, the thread is elastodiene.

A.4 Thread covering

Knitted elastane and elastodiene and inlaid elastodiene yarns should be covered using one of the following methods.

- a) Double covering: wrapping two spirals of non-elastic threads in opposite directions around an elastic core.
- b) Single covering: wrapping one spiral of non-elastic threads around an elastic core.
- c) Stitch covering: knitting a chain stitch of a non-elastic yarn around an elastic core.
- d) Core spinning: spinning a non-elastic staple yarn around an elastic core.
- e) Core twisting: twisting together a non-elastic yarn with an elastic yarn.
- f) Air jet covering: intermingling an elastic yarn with a synthetic textured non-elastic yarn.

A.5 Draft during covering

Elastane and elastodiene manufacturers' recommendations for maximum extension should be followed because the elastic core extension during covering, i.e. in the fully stretched state, influences strongly the wear life of hosiery.

A.6 Thread linear density and thread thickness

The minimum linear density of elastane and non-elastic threads and the minimum thickness for elastodiene threads should be as given in tables A.1 and A.2.

Exact details of type and thickness should be obtained from the yarn manufacturer for elastane. The thread should not lose more than 25 % of its original mass.

A method of measuring thickness is given in A.7.

Table A.1 Minimum linear density or thread thickness of inlaid threads

| Material of elastic thread | Core | Sum total of linear density of all coverings |
|----------------------------|----------------------|--|
| Elastodiene | 100 gauge (circular) | 22 dtex |
| Elastane | 310 dtex | - |

Table A.2: Minimum linear density or thread thickness of knitted threads

| Material of elastic thread | Core | Sum total of linear density of all coverings |
|----------------------------|-----------|--|
| elastane | 33 dtex | 33 dtex |
| elastodiene | 140 gauge | 44 dtex |

| | | |
|--------------------------|---------|--|
| other non-elastic thread | 55 dtex | |
|--------------------------|---------|--|

A.7 Method of measuring thread thickness

A.7.1 Introduction

The method applies to natural, synthetic and textured yarns, elastane and elastodiene and to establishing the type of covering used, i.e. single or double.

NOTE: It is not possible to ascertain the exact thickness of elastane after it has been subjected to treatment during covering because variations from the original thickness can be significant.

A.7.2 Preparation of test samples

A.7.2.1 Atmospheric conditioning

Condition the test sample in accordance with ISO 139.

A.7.2.2 Removal of yarn from knitted garment

Cut open a sample piece to enable the yarn to be pulled out to obtain a total length of at least 1000 mm, with the minimum length of single pieces of thread being 100 mm. Take care to ensure that the yarn is not overstretched when being pulled out and that none of the filaments are damaged. Remove the covering of covered yarn carefully and record the method of covering.

A.7.3 Apparatus

A.7.3.1 Instrument for measuring length, comprising a vertical measure with the scale graduated in millimetres, having a clamp for securing the test sample.

A.7.3.2 Cutting instrument, e.g. razor blade.

A.7.3.3 Weights, to establish pre-tension.

A.7.3.4 Balance, with an accuracy of not less than 0,1 % of the mass of test sample.

A.7.4 Procedure

A.7.4.1 Elastodiene

Determine the yarn thickness in accordance with ISO 2321.

A.7.4.2 Elastane

Remove the covering of elastane carefully. Boil the bare sections of yarn in distilled water for approximately 2 min and test as described in A.7.4.3.

For pre-tensioning, use the values given in table A.3. If the yarn still curls slightly when applying the pre-tension weight, then increase the pre-tension weight (to a maximum of 0,02 cN/tex) until the yarn has straightened.

A.7.4.3 Non-elastic yarns

Lay out test yarns for 5 h, ensuring that they are tension-free.

Secure one end of the test sample in the top clamp and place a pre-tension weight in accordance with table A.3 at the bottom, releasing it slowly. Secure the weight with a spring clip at the end of the test sample.

The setting time of the load is 1 min. Ensure that the test sample does not twist whilst clipping on the pre-tension weight and during the setting time, so that no existing twists are lost.

Measure the length of the test sample under pre-tension on the vertical measure and express it in millimetres, then cut it at each clamp and weigh it to an accuracy of 0,1 %.

A.7.5 Test results

Evaluation and presentation shall be in accordance with ISO 1144.

Table A.3: Pre-tension weights

| Yarn | Pre-tension weight cN/tex |
|---|------------------------------|
| Elastane | 0,01 ± 0,0025 |
| Natural yarn and non-texturized synthetic yarns | 0,5 ± 0,1 |
| Texturized threads | 2,0 ± 0,2 |

A.8 Design

A.8.1 Knitting construction

Hosiery should be produced with either of the following knit types.

a) Double face, flat bed knitted hosiery with seam, with elastic inlaid threads or with elastic inlaid and knitted elastic threads. The inlaid thread should occur in at least every second course.

If compression class I hosiery is knitted without inlaid threads a minimum linear density of 156 dtex in at least every other course should be used.

The form of the hosiery should be achieved by changing the number of needles.

b) Single face, circular knit hosiery (seamless) with inlaid elastic threads or with inlaid elastic threads and knitted elastic threads. The inlaid thread should occur in at least every second course.

If compression class I hosiery is knitted without inlaid threads a minimum linear density of 156 dtex in at least every other course should be used.

The form of the hosiery should be achieved by varying the tightness of the courses and the tension of the knitted threads.

A.8.2 Range limits for girth for circular knitted hosiery

When knitting a range of hosiery, a single set of number of stitches (e.g. 314) should not cover

a greater range of girth than a factor of 3.3 between the smallest measure and the widest measure to be covered. For a greater range, two or more sets of stitch numbers of the same gauge should be used.

Annex B (normative)

Method for test for mechanical properties of hosiery.

B.1 Principle

Measurement of the force exerted by hosiery across its width when it is stretched simultaneously both sideways and lengthways according to its size specifications. The measurement force is transformed into pressure using the Laplace formula.

This method is intended for determining the mechanical properties of hosiery.

Other methods (e.g. those listed in annex D) may be used provided that the results are equivalent to those from this reference method.

Mechanical properties are determined by measuring at certain points the circumferential force or pressure that is necessary to stretch the hosiery to the extents according to its size designation.

B.2 Apparatus

B.2.1 Washing machine, conforming to ISO 6330.

B.2.2 Device for marking of measuring points, (see figure B.1) comprising a base-board, on which a clamp is mounted that is capable of fixing a foot frame (see figure B.2) made from a round metal bar of approximately 6 mm-diameter. A centimetre scale and measuring point marks may be placed on the base-board. For the flattened foot shape, set the floor reference at 1,0 cm above the lowest part of the foot frame under the clamp position.

B.2.3 Metre rule, graduated in millimetres.

B.2.4 Gripping device, in accordance with figure B.3 together with either:

a) a distorting parallelogram to prevent necking;

or

b) a set of stretcher bars to prevent necking, as in figure B.4.

B.2.5 A tensile strength machine, with a constant traverse facility.

B.2.6 Coloured felt pen.

B.2.7 Devices for force or pressure measurement, calibrated in accordance with ISO 376.

B.3 General conditions for test

B.3.1 Identification of hosiery

Identify the hosiery in accordance with the requirements of this standard and permanently mark it for later identification.

B.3.2 Washing

Before testing, wash the hosiery once according to ISO 6330/6A, followed by 2 min hydroextraction and a flat drying process according to mode C of ISO 6330.

Ensure that the hosiery gains weight during the ensuing conditioning.

B.3.3 Conditioning

Condition the hosiery for at least 12 h immediately prior to testing, and carry out measurements in an atmosphere according to 2.2.1 of ISO 139.

B.3.4 Number of test samples

Test two test samples of each size and length.

B.3.5 Marking of measuring points

Measure compression at the measuring points specified in 10,3.

B.3.6 Marking of the measuring points

With the foot frame inside the foot, fix the hosiery in the ground clamp.

Stretch the hosiery lengthwise so that the compressive part takes up the specified length, and fix it at the welt by pins or an appropriate clamp.

Mark the appropriate measuring points in accordance with the length specification with a coloured felt pen.

B.3.7 Measurement of minimum and maximum sizes

Take measurements at the minimum and maximum girths and at the minimum and maximum lengths stated by the manufacturer.

If measurements at different girths and lengths are taken from the same test sample without intermediate relaxation of the hosiery, begin measuring at the smallest girth or length.

B.3.8 Control of length elongation

During measurement, stretch the area under measurement correctly in accordance with the relevant length specifications, and avoid any necking.

B.3.9 Slope

If slope is to be measured make force (pressure) measurements for measuring points *B* and *B1* for girths that are 1 cm smaller and 1 cm greater than the relevant girth specification(s).

B.3.10 Practical elongation

Measure initial circumferences to be used for calculation of practical elongation either by flat width or by using a preload on the measurement area not exceeding:

5 cN/cm for Ccl I and Ccl II;
10 cN/cm for Cc III and Ccl IV.

Stretch the area of measurement to its on-leg length during this procedure.

B.4 Method of test for mechanical properties

B.4.1 Procedure

B.4.1.1 Prepare the hosiery in accordance with B.3.1 to B.3.3.

B.4.1.2 Mount the leg of the hosiery onto the device for marking of measuring points as described in B.3.6.

B.4.1.3 Draw the measurement points on the front and back of the hosiery leg with a felt pen, using the rule or the reference points on the device. Follow the courses to draw the

measurement points on the back.

Remove the hosiery from the marking device, and allow it to rest flat on a surface for at least 2 h.

B.4.1.4 Repeat B.4.1.2 and B.4.1.3.

Mark the mean of the two positions on the hosiery leg, so as to indicate the test points.

B.4.1.5 Set the traverse of the tensile strength machine with the rods in position as follows :

a) Set the machine zero with the rods just touching (equivalent to 3,0 cm wrap of fabric around the rods).

b) Set the maximum machine setting to $\frac{(\text{specified girth} - 3)}{2}$ cm.

c) Set the minimum machine setting to $\frac{(\text{unstretched girth} - 3)}{2}$ cm.

B.4.1.6 Position the test sample on the tensile strength machine and introduce the needle rod inside the hosiery, where the needles going through the fabric can move easily around the rod. Either:

a) press the fabric onto the parallelogram pins along the marked lines across the leg; or

b) press the fabric onto the pins of the spacer bars along the marked lines across the leg, at intervals of approximately 7 mm.

B.4.1.7 Carry out the tensile test, stretching the test sample continuously five times from the minimum setting to the maximum setting and return, with a final extension to the maximum setting, at a traverse rate of 200 mm.

Note the strength F , in centiNewtons, immediately after the completion of the sixth cycle.

B.5 Calculation and expression of results

B.5.1 General

Calculate the compression in accordance with the Laplace formula, from the expression:

$$P = \frac{F \times \pi}{L \times C}$$

where

P is the compression expressed in hectopascals;

F is the strength immediately after the sixth cycle expressed in centiNewtons;

L is the length of the middle rod of the grip, expressed in centimetres; (3 cm in the case of the device described in B.2.4 and B.2.5);

C is the girth at the measuring point, expressed in centimetres.

B.5.2 Compression

Calculate compression (P) for 1 cm of length of the hosiery leg. Where forces (F) have been measured calculate the pressure exerted on the leg in accordance with the Laplace formula, from the expression:

$$P_I = \frac{F_I \times 2\pi}{G_I}$$

where

P_I is the compression at measuring point I , expressed in hectopascals;

F_I is the tension force for 1 cm of length of the hosiery leg at measuring point I expressed in Newtons per centimetre, with the extension corresponding to the relevant girth;

G_I is the girth at measuring point I expressed in centimetres.

B.5.3 Residual pressure

Calculate the residual pressure (RP_I) at measuring point I from the expression :

$$RP_I = \frac{P_I \times 100}{PB} (\%)$$

where

RP_I is the residual pressure at measuring point I expressed as a percentage;

P_I is the compression at measuring point I expressed in hectopascals;

PB is the compression at measuring point B expressed in hectopascals.

NOTE: This calculation is based on the compression at measuring point B being taken as 100 %.

B.5.4 Practical elongation

Using the results of measurements in accordance with B.3.10, calculate the practical elongation (EP) from the expression :

$$EP_I = \frac{G_I - 2W_I}{2W_I} \times 100 (\%)$$

where

EP_I is the practical elongation at measuring point I expressed as a percentage;

G_I is the girth at measuring point I expressed in centimetres;

W_I is the flat width of the hosiery at measuring point I , expressed in centimetres.

B.5.5 Slope (stiffness)

Using the results of measurements in accordance with B.3.9, calculate the change of compression with girth for measuring points *B* and *B1* from the expression :

$$S_U = \frac{P_{(U+1)} - P_{(U-1)}}{G_{(U+1)} - G_{(U-1)}}$$

where

U is measuring point *B* or *B1*;

S_U is the stiffness at measurement point *U*, expressed in hectopascals per centimetre (change of girth);

G_(U+1), *G_(U-1)* are the girths respectively 1 cm bigger or smaller than the girth at *U*, expressed in centimetres;

P_(U+1), *P_(U-1)* are the compressions at girths *G_(U+1)* and *G_(U-1)*, expressed in hectopascals.

NOTE: If the slopes assessed for minimum and maximum size specification do not differ by more than 20 %, calculate an average value. Otherwise, report slopes separately for the minimum and maximum sizes.

B.5.6 Test report

The test report shall be compiled in accordance with 4.3 of EN 45001, and shall include the following particulars:

- a) identification of the hosiery tested (manufacturer, name and type of hosiery);
- b) size (girth and length);
- c) the method used;
- d) the number of test samples tested;
- e) compression at measuring point B expressed in hectopascals;

NOTE: Compression may also be expressed in millimetres of mercury¹⁾.

- f) compression class;
- g) residual pressure at all relevant measuring points and its correspondence with the limits specified in this standard;
- h) practical elongation at all relevant measuring points and its correspondence with the limits specified in this standard;
- i) reference to this European Standard;

¹⁾ 1 mmHg = 1,333 hPa

- j) deviations from this European standard;
- k) if appropriate, pressure profile;
- l) if appropriate, slope at measuring points *B* and *B1*;
- m) if appropriate, comparisons with the reference method.

Annex C (normative)

Method of determination of extensibility of hosiery

Cut open the hosiery lengthwise. Cut out test samples in both test directions (length and width) of size 10 cm long by 50 mm wide at measuring points *B* and at the uppermost measuring points (*D*, *F* or *G*), keeping the stitches and courses straight. Overlock the lengthwise edges of the test pieces in the stretch direction with highly stretchable overlock seams.

Clamp the test sample into a tensile tester, keeping the width at 50 mm by holding the sample at equal distances on three spreader bars.

Apply a load of 5 daN to the test piece at a speed of 55 mm per minute. Record the resulting stretch (l_1) in millimetres.

Determine the extensibility E , as a percentage, using the expression :

$$E = \frac{l_1 - l_0}{l_0} \times 100 \%$$

where

l_1 is the stretch at a load of 5 daN expressed in millimetres;

l_0 is 50 mm;

E is the elongation expressed as a percentage.

Repeat the test and record the average value.

Annex D (informative)

Examples of methods of compression testing

Examples of systems for measuring the compression of hosiery are as follows:

| Name of method | Information from |
|-----------------------|--|
| HATRA | Segar Design 14 Cheslyn Drive Aspley Nottingham NG8 3NB UK |
| HOSY | Forschungsinstitut Hohenstein Schloss Hohenstein D - 7124 Bonningheim Germany EMPA Unterstrasse 11 Postfach 977 CH - 9001 St. Gallen Switzerland |
| ITF | ITF-LYON B.P. 60 F-69132 Eculy Cedex France Centexbel Grotesteeweg Noord 2 B-9710 Gent (Zwijnaarde) Belgium |
| TNO | TNO-Fibre Research Institute PO Box 110 NL-2600 AC Delft Netherlands |
| MST | (Medical Stocking Tester, no longer in production) |

Annex E (informative):

Clauses of this European Standard addressing essential requirements or other provisions of EU Directives.

This European standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association and supports essential requirements of EU directive 93/42/EEC of 14 June concerning medical devices.

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The Following Clauses for this standard are likely to support requirements of Council Directive 93/42/EEC of 14 June concerning medical devices: 4, 5, 6, 7, 8, 9, 10, 11.

Compliance with the clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

| Clauses/sub-clauses of this European Standard | Corresponding annex/paragraph of Directive (specify Directive number, e.g. 93/42/EEC) | Remarks |
|---|---|---------|
| 4 | | |
| 5 | | |
| 6 | | |
| 7 | | |
| 8 | | |
| 9 | | |
| 10 | | |
| 11 | | |

