DRAFT FOR DEVELOPMENT

DD ENV 12718:2001

Medical compression hosiery

ICS 11.120.20

National foreword

This Draft for Development is the English language version of ENV 12718:2001.

This publication is not to be regarded as a British Standard.

It is being issued in the Draft for Development series of publications and is of a provisional nature because it is most unlikely that the method of testing the durability of hosiery that has been in course of development in the European committee CEN/TC 205/WG 2 will now be completed. However it is believed that the requirements and recommendations of this DD ENV as it stands will be valuable to industry and the user, in particular to allow acquisition of experience of the compression classes and the use of the method for measuring compression. This experience will be taken into account together with any aspects of durability testing when reviewing this DD ENV. DD ENV 12718 should be applied on this provisional basis, so that information and experience of its practical application may be obtained.

Comments arising from the use of this Draft for Development are requested so that UK experience can be reported to the European organization responsible for its conversion into a European Standard. A review of this publication will be initiated 2 years after its publication by the European organization so that a decision can be taken on its status at the end of its three-year life. The commencement of the review period will be notified by an announcement in *Update Standards*.

According to the replies received by the end of the review period, the responsible BSI Committee will decide whether to support the conversion into a European Standard, to extend the life of the prestandard or to withdraw it. Comments should be sent in writing to the Secretary of BSI Technical Committee CH/39, Compression hosiery and elastic hose supports, at 389 Chiswick High Road, London W4 4AL, giving the document reference and clause number and proposing, where possible, an appropriate revision of the text.

A list of organizations represented on this committee can be obtained on request to its secretary.

Attention is drawn to DD ENV 12719 *Medical thrombosis prophylaxis hosiery* and the following related British Standards: BS 6612:1985 *Specification for graduated compression hosiery*, BS 7563:1999 *Specification for non-prescriptive graduated support hosiery* and BS 7672:1993 *Specification for compression, stiffness and labelling of anti-embolism hosiery*.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled "International Standards Correspondence Index", or by using the "Find" facility of the BSI Standards Electronic Catalogue.

This Draft for Development, having been prepared under the direction of the Health and Environment Sector Policy and Strategy Committee, was published under the authority of the Standards Policy and Strategy Committee on 12 September 2001

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PRÉNORME EUROPÉENNE

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ENV 12718

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ICS 11.120.20

English version

Medical compression hosiery

Bas médicaux de compression

Medizinische Kompressionsstrümpfe

This European Prestandard (ENV) was approved by CEN on 23 June 2001 as a prospective standard for provisional application.

The period of validity of this ENV is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the ENV can be converted into a European Standard.

CEN members are required to announce the existence of this ENV in the same way as for an EN and to make the ENV available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the ENV) until the final decision about the possible conversion of the ENV into an EN is reached.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Contents

Foreword

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

This European Prestandard 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(s).

For relationship with EU Directive(s), see informative annex ZA, which is an integral part of this prestandard.

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

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this European Prestandard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

An important property of hosiery is its durability, i.e. the retention of its designated 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.

1 Scope

This European Prestandard specifies requirements and gives test methods for medical compression hosiery, including custom-made hosiery (class 030606, EN 29999), 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. This European Prestandard does not give requirements connected with the manufacture of hosiery.

NOTE Manufacturing methods that have been shown by experience to be satisfactory are given for information in annex A.

2 Normative references

This European Prestandard 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 Prestandard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 980, *Graphical symbols for use in the labelling of medical devices*

EN 1041, *Information supplied by the manufacturer with medical devices*

EN 23758, *Textiles — Care labelling code using symbols (ISO 3758:1991)*

EN 26330:1993, *Textiles — Domestic washing and drying procedures for textile testing (ISO 6330:1984)*

ISO 376, *Metallic materials — Calibration of force-proving instruments used for the verification of uniaxial testing machines*

3 Terms and definitions

For the purposes of this Prestandard, the following terms and 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 rubber thread thickness
conventional count of a rubber thread
gauge number round (not square)
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 designated 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 Prestandard

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 Prestandard 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 Prestandard

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 grams of 10 000 m of yarn expressed in dtex

NOTE The basic unit is the tex (10 dtex = 1g/km)

4 Compression classes

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

NOTE 1 The package of hosiery compression Class 1 can be labelled in addition as follows:

— 15 mmHg (20hPa) to17 mmHg (23hPa): Class I.L (low)

— 18 mmHg (24hPa) to 21 mmHg (28hPa): Class I.H (high)

NOTE 2 Class A reflects the practice in some European countries but it is currently not supported by sufficient scientific evidence.

Table 1 — Compression classes

Compression class		Compression at the ankle[1)]	
		hPa	mmHg[2)]
Ccl A	light	13 to 19	10 to 14
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 mmHg = 1,333 hPa.

5 Nominal 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 Figure 1 and Table 2.

5.2 Measurement of length

If measured, lengths shall be measured and codes allocated in accordance with Table 3.

5.3 Measurement of girth

If measured, 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 Prestandard, this system of sizes is specified based on the ankle girth (cB).

5.4.1 Length

Except for custom-made hosiery, lengths and range of length shall be chosen from Table 5.

5.4.2 Girth

Except for custom-made hosiery, girths and range of girths shall be chosen from Table 6.

5.5 Designation of type and size of hosiery

Hosiery shall be designated by the type code according to Table 7 followed, except for custom-made hosiery, 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

Where values for intermediate measuring points fall in the same vertical column of Table 6 or on the straight lines drawn from the smallest and widest ankle dimension to the smallest and widest girth dimension at the upper end of the hosiery, no further information is required.

If values of intermediate measuring points don't fall on the straight lines, then a diagrammatic representation of the range of leg sizes that the hosiery is intended to fit shall be supplied either on the package, or in a leaflet in the package. The same applies in the figurative sense to the dimensions of the length given in Table 5.

NOTE 1 An example of type and size designation is AD 22-24 (34-36/41-45)

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);

41-45 is the range of length (lD) (41 cm to 45 cm).

For the measuring points between the ankle and the upper end of the hosiery according to Figure 1 the range of girths shall be marked according to clause 12.

NOTE 2 A further example of type and size designation is AF 22-24 (46-56/60-64)

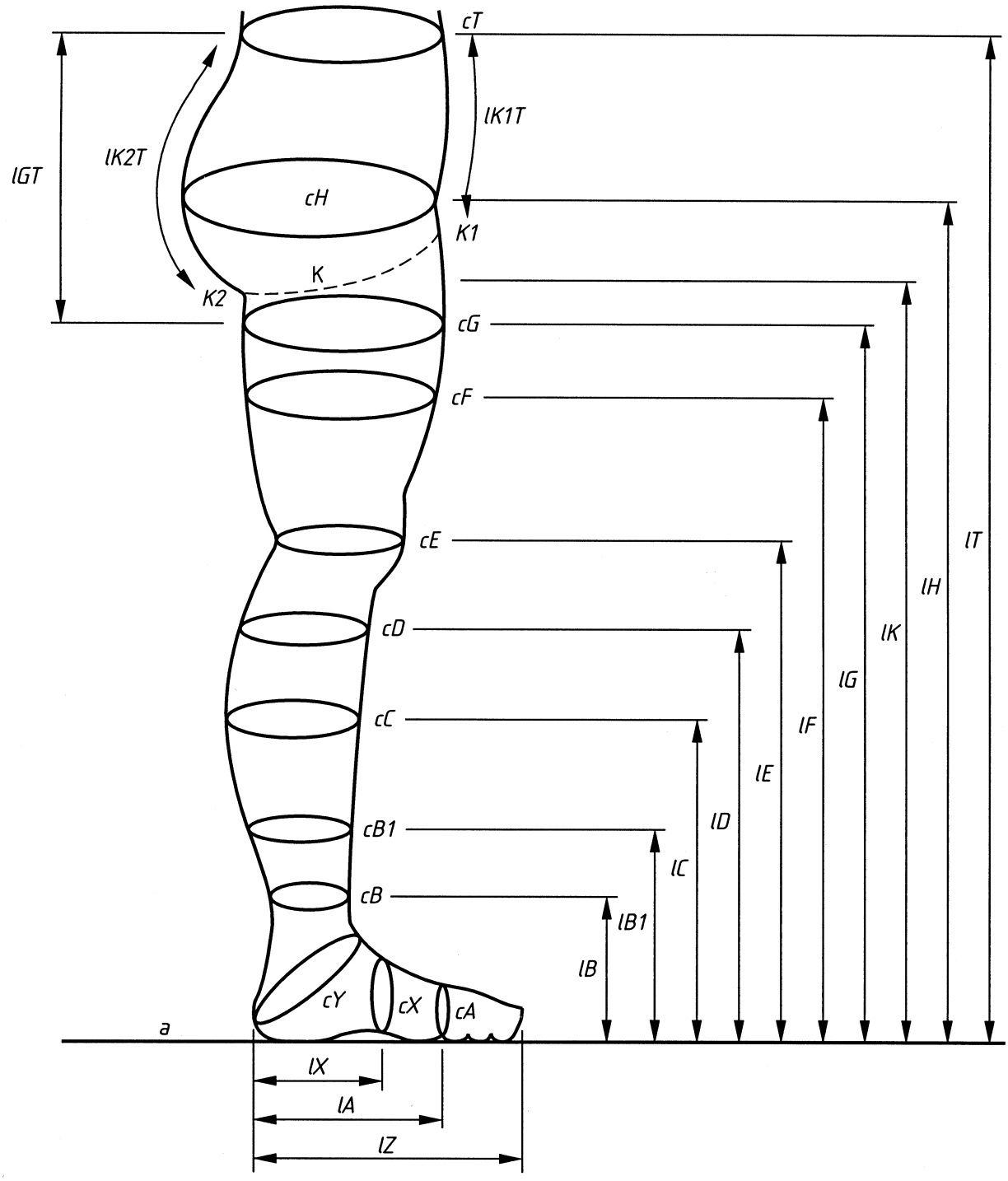
where

AF is the code for mid-thigh hosiery;

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

46-56 is the range of girth at the upper end of the hosiery (46 cm to 56 cm);

60-64 is the range of length (ID) (60 cm to 64 cm)



NOTE Measurements should preferably be taken at the patient's leg in a standing position.

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

Table 2 — Nominal measuring points (see Figure 1)

Measuring point	Description of the measuring point
a	sole of the foot at the heel
A	forefoot at the implantation of the toes
B	ankle at the point of its minimum girth
B1	point at which the Achilles tendon changes into the calf muscles
C	calf at its maximum girth
D	just below the tibial tuberosity
E	centre of the patella and over the back of the knee
F	between K and E
G	5 cm below K with the patient in the upright position
H	greatest lateral trochanteric projections of the buttock
K	centre point of the crutch
K1	level at the pubic symphysis
K*2*	level at the infra-gluteal fold
T	natural waistline
X	middle of the foot
Y	instep
Z	tip of toe

Table 3 — Nominal measurement of length

Length code[2)]	Length of the leg
lB	distance measured from a to B
lB1	distance measured from a to B1
lC	distance measured from a to C
lD	distance measured from a to D
lE	distance measured from a to E
lF	distance measured from a to F
lG	distance measured from a to G
lH	distance measured from a to H
lK	distance measured from a to K
lT	distance measured from a to T
lX	distance measured from the most prominent part of the heel to X
lA	distance measured from the most prominent part of the heel to A (foot length without toe)
lZ	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)
lGT[1)]	distance measured from G to T
lK1T[1)]	distance measured from K1 to T
lK2T[1)]	distance measured from K2 to T

[1)] For panty hose only, measured along the body.

[2)] l = length.

Table 4 — Nominal measurement of girth

Girth code[1)]	Girth of the leg
cA	girth measured at A
cB	girth measured at B
cB1	girth measured at B1
cC	girth measured at C
cD	girth measured at D
cE	girth measured at E
cF	girth measured at F
cG	girth measured at G
cH	girth measured at H
cT	girth measured at T
cX	girth measured at X
cY	girth at Y, measured with the foot in maximum dorsal flexion
[1)] c = girth.	

Table 5 — Nominal leg lengths for standard size hosiery

Length code	Length cm						
	short hosiery		normal hosiery			long hosiery	
lG	65	68	71	74	77	80	83
lF	54	57	59	62	64	67	69
lE	41	43	45	47	49	51	53
lD	35	37	38	40	41	43	44
lC	27	29	30	32	33	35	36
lB1	19	20	21	22	23	24	25
lB	10	11	11	12	12	13	13

Table 6 — Nominal leg girths

Size of hosiery																												
Girth code	**Slender supplement**					18	19	20	21	22	23	24	25	26	27	28	29	30	**Sturdy supplement**									
Circumferences in cm																												
cG	43	45	46	48	49	51	52	54	55	57	58	60	61	63	64	66	67	69	70	72	73	74	76	77	79	80		
cF	35	37	38	40	41	43	44	46	47	49	50	52	53	55	56	58	59	60	61	62	63	65	66	68	69	71		
cE	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	---		
cD	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	49	---	---		
cC	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	---	---	---		
cB_1	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	---	---	---	---		
cB	---	---	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	---	---	---	---			

Table 7 — Designation of types of hosiery

Type of hosiery	Code
Below-knee hosiery	AD[1)]
Mid-thigh hosiery	AF[2)]
Thigh hosiery	AG[3)]
Single leg panty	AGTL[4)], AGTR[5)]
Panty hosiery	AT[4)]

1) AD: Upper end of hosiery corresponds to measuring position D. An area of maximum 10 mm below can be less or non-compressive.

2) AF: Compressive up to measuring position F. There can be a less or non-compressive welt or part above.

3) AG: Upper end of hosiery corresponds to measuring position G. An area of maximum 50 mm (stretched condition) below upper end can be less or non-compressive.

4) AGT/AT: Compressive at least up to measuring position G.

5) L = left leg; R = right leg.

6 Heel

Hosiery shall have 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.

7 Seams

Seams shall be smooth on the inside of the hosiery.

NOTE Seams can be overlocked.

Testing shall be carried out by visual inspection.

8 Edges

Edges shall be non-fray.

Testing shall be carried out by visual inspection.

9 Achievement of compression profile

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

NOTE There can 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 the measuring points B, B1, C, D, E, F and G, where appropriate. The stretch capability in the longitudinal direction shall be at least 30 % at the measuring points B, B1, C, D, E, F and G, where appropriate.

Testing shall be carried out in accordance with annexes B and C.

10.2 Practical elongation

The practical elongation shall be not less than 15 % and not more than 140 % at the measuring points B, B1, C, D, E, F and G, where appropriate.

Testing shall be carried out in accordance with annex B.

10.3 Residual pressure

In order to avoid irregularities of the pressure profile along the leg, pressure shall be measured at measuring points B, B1, C, D, E, F and G, where applicable (see B.2.4).

The residual pressures shall be calculated for measuring points B1, C, D, E, F and G where applicable (see B.5.2).

The residual pressures (pressure profile) of the hosiery shall lie within the area determined by the values given in Table 8.

NOTE This should apply also, if at measuring points D and F or G, where applicable, residual pressure is calculated from the pressures obtained for the highest girth at measuring point B and for the lowest girth given by the producer for D, F, and G, as well as when calculated for the lowest given for B and the highest ones for D, F, and G.

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. At the E-level the residual pressure can be lower than which follows from the interpolation of the values for D and F.

With hosiery bearing an adhesive welt, at an upmost area not smaller than 50 mm, compression can be 15 percentage points higher than measured for the elastic knit directly below, but the residual pressure of the adhesive welt shall not exceed the limits given in Table 8.

Testing shall be carried out in accordance with annex B.

Table 8 — Ranges of pressure profiles

% of compression exerted at ankle			
Compression Class	**at B1**	**at C and D**	**at F or G**
Ccl A	70 to 100	50 to 80	20 to 60
Ccl I	70 to 100	50 to 80	20 to 60
Ccl II	70 to 100	50 to 80	20 to 50
Ccl III	70 to 100	50 to 80	20 to 40
Ccl IV	70 to 100	50 to 80	20 to 40

10.4 Durability of compression

NOTE In normal use hosiery should keep the compression according to its compression class for approximately 6 months. Suitable hosiery manufacturing methods are given in annex A (informative).

11 Packaging

Except for custom-made hosiery, hosiery shall be packaged so that exposure of the hosiery to light is minimized.

12 Marking and instructions for use

The information supplied by the manufacturer shall comply with EN 980 and EN 1041.

Specification for ranges of length and girth which differ from Table 5 and Table 6 according to 5.5, shall be made available for the supplier/distributor in a suitable form.

12.1 Marking of hosiery

Hosiery shall be durably marked at least with the following information:

a) name or trade name of the manufacturer or authorized representative or importer within EEA;

b) name of the product;

c) fibre content (unless marked on the package);

d) compression class;

e) either the type and size designation as specified in 5.5 or an indication that the hosiery is custom made;

f) washing and treatment symbols in accordance with EN 23758.

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 authorized representative or importer within EEA;

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 designation as specified in 5.5 or an indication that the hosiery is custom made;

NOTE The following information can also be given.

g) Stiffness (test method annex B);

h) Graphical or tabulated representation of the range of leg measurements that the hosiery is intended to fit.

12.3 Handling and usage

The package or a leaflet with the hosiery shall contain at least the following information:

a) instructions for washing and drying;

b) instructions for handling and usage;

c) contra-indications and warnings for misuse.

NOTE A diagrammatic representation of the range of leg sizes that the hosiery is intended to fit can also be given.

Annex A
(informative)

Hosiery manufacturing methods

A.1 Introduction

An important property of hosiery is 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 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

Identification of elastic materials (e.g. elastane, elastodiene)

A.3.1 Chemical identification of elastane and elastodiene in hosiery

Chemical identification of elastic materials in hosiery.

A.3.2 Apparatus and reagents

A.3.2.1 Microscope

A.3.2.2 Microscope slides

A.3.2.3 Acetic acid solution, 98 % V/V in water.

A.3.2.4 Formic acid solution, 85 % V/V in water.

A.3.3 Test procedure

Mix three parts of acetic acid solution (A.3.2.3) and one part of formic acid solution (A.3.2.4).

Place the test sample on a microscope slide (A.3.2.2). 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 elastane and 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 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 (see Note: A.7.1)

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	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 (round)	44 dtex
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 EN 20139:1992.

A.7.2.2 Removal of yarn from knitted hosiery

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 measure with the scale in millimetres, having clamps for securing the test sample, and having the possibility to apply a pre-tension on the yarn.

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

A.7.3.3 Weights, to establish pre-tension when required.

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 one clamp and apply the pretension at the other end in accordance with Table A.3.

The setting time of the load is 1 min. Ensure that the test sample does not twist whilst applying 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 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 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 testing compressive 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 designation. The measured force is transformed into pressure using the Laplace formula.

Other measuring devices (e.g. those listed in annex D) can be used provided that the results obtained correlate to those obtained from the device used in this reference method with an accuracy of ± 10 %.

Compressive properties are determined by measuring the circumferential force at certain positions necessary to stretch the hosiery specimen to the extent according to its size designation.

B.2 General conditions

B.2.1 Identification of hosiery

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

B.2.2 Number of test samples

For each size and length of standard hosiery to be tested, test at least two specimens. For custom made hosiery test one specimen.

B.2.3 Measuring positions

Measure compression at the measuring positions specified in 10.3.

B.2.4 Measurement of compression at minimum and maximum sizes

If the manufacturer states a range of girths and/or lengths, take compression measurements at both minimum and maximum girths for each measuring position, and/or both the minimum and maximum lengths.

If the difference between minimum and maximum girths indicated by the manufacturer does not exceed 10 % (based on the minimum girth) for each applicable measuring position, compression measurements are determined at minimum girths only.

If the difference between minimum and maximum lengths indicated by the manufacturer does not exceed 15 % (based on the minimum length), compression measurements are determined only at the mean of the minimum and maximum values, rounded down to whole numbers.

B.2.5 Stiffness

If stiffness is to be determined, take force (pressure) measurements on the hosiery at reference point B for girths that are 1 cm smaller and 1 cm larger than the ankle girth stated by the manufacturer. Always measure the smallest girth first.

B.3 Apparatus

B.3.1 Washing machine, conforming to EN 26330:1993.

B.3.2 Device for marking of measuring positions

The device shall comprise a marking-board (see Figure B.1), on which an adjustable clamp is mounted that is capable of fixing the lower end of the hosiery with either one of two different systems as follows:

a) for circular knitted specimens, a system of clamps or needles shall be used (see Figure B.2a);

b) for flat knitted specimens, a foot frame (see Figure B.2b) made from a round metal bar of approximately 6 mm diameter shall be used.

B.3.3 Metre rule, graduated in millimetres.

B.3.4 Coloured felt tipped pen.

B.3.5 Gripping device, in accordance with Figures B.4 and B.5, with:

a) a distorting parallelogram to prevent necking, as in Figure B.4.

b) a set of stretcher bars to prevent necking, as in Figure B.5.

NOTE Referring to Figure B.5, the hosiery is stretched across its width by the use of rods with embedded needles. The rods are positioned inside the hosiery and the needles pushed through the fabric at marked positions. Clamps attached to a tensile tensometer are used to grip the needles in order to stretch the hosiery at the given measuring position.

Three rods are used to hold one side of the specimen. Their needles are gripped to hold the rods in a straight line, with the outer needles held rigidly to the traverse beam, and the middle needle held to the load cell of the tester.

The middle rod is separated from the outer rods, so that it is free to give an accurate measure of the force in the middle part of the stretched fabric. The forces on the outer rods, are transmitted directly to the traverse beam. Thus the end effects that occur at the outer ends of these rods, due to the distortion of the fabric at these points, do not affect the measurement accuracy.

In order to ensure that the three rods are aligned for the test, they can be held in a close fitting sleeve before positioning inside the specimen. Then the sleeve is immediately removed. These rods are to be held in position on the machine.

The other side of the hosiery is held by a single rod, with two needles. The unit gripping these needles can pivot on its attachment to the base of the tester, which allows for measurements on tapered areas of a hosiery.

All the rods are 6 mm in diameter.

Each of the upper rods are 30 mm in length. During measurement they shall not touch. The lower rod is equal in length to the total length of the three upper rods.

The fabric at each side of the measurement position is impaled upon vertical rows of pins, in order to keep the area of measurement stretched along the hosiery length, and avoid necking. The pins can be part of parallelograms which expand vertically with the fabric, as shown in Figure B.4, or they can be attached to each end of the "stretcher" bars, as shown in Figure B.5.

The vertical spacing of the pins should be such that, at maximum stretch, there is not more than 20 mm between adjacent pins.

B.3.6 A tensile tensometer, with a constant traverse facility.

B.3.7 Devices for force measurement, calibrated in accordance with ISO 376.

B.4 Test procedure

B.4.1 Washing

Before testing, wash the hosiery once according to EN 26330: 1993/6A, followed by hydroextraction for not more than 2 min and a flat drying process according to mode C of EN 26330:1993.

Ensure that the hosiery gains weight during the ensuing conditioning.

B.4.2 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 EN 20139:1992.

B.4.3 Definition and marking of the measuring points

B.4.3.1 Place the leg of the hosiery onto the marking and measuring device to enable the marking of the measuring points and fix the hosiery to the ground clamp as follows:

a) Circular knitted hosiery

Fix the lower end (the first course above the heel surrounding the hosiery) of the stocking in the fixing device of the marking board and adjust the movable clamp so that the lower end is positioned at 45 mm on the graduated scale (this fixing position is to take account of the height of the heel from the sole of the foot).

b) Flat knitted hosiery

With the foot frame inside the foot, fix the hosiery in the ground clamp. Set the lowest position of the heel on a position of - 2,5 cm below the zero point of the scale.

B.4.3.2 Stretch the hosiery lengthways so that the upper end of hosiery (AD, AG) and/or compressive knit as appropriate (AF, AGT, AT hosiery) is stretched up to its specified length, and fix the upper end by pins or an appropriate clamp.

To be able to measure compression by means of the reference method, at either the upper end of the garment or the compressive knit, the stated length at this point has to be lowered by 15 mm in order for the middle rod to be fully covered by the material to be tested. With hosiery bearing a less or non-compressive section above the uppermost measuring point, measurement is determined with the middle rod covered by the elastic knit, the end of the rod being near the change in construction.

With hosiery having an adhesive welt, two measurements are performed: One with the middle rod covered by the welt, and another one with the middle rod covered by the elastic knit below. Each time one end of the middle rod is positioned near the change from the elastic knit to the welt.

B.4.3.3 At each measurement position, mark the following measurement points on the centre line of the hosiery leg with a felt pen, using the graduated scale or the reference lines on the device. (see diagram B.3 which illustrates the points marked on the centre line for each measuring position).

a) The centre of the measurement position.

b) Two equi-spaced points, at the spacing of the needle clamps which hold the outer needle rods in the gripping device.

c) Two equi-spaced points, at the spacing of the stretcher pins.

Follow the courses from the marked positions, to mark the three upper and two lower needle insertion points, and to mark the lines for the stretcher pins.

B.4.4 Unstretched girth (C_{min})

Measure the lay flat width W (cm) at each measuring position with the stocking laying flat without preload and multiply by 2 to obtain the girth.

B.4.5 Calculation of minimum and maximum rod distances

a) Calculate the minimum distance between the rods in position as follows:

$$L_{\min} = \frac{(\text{unstretched girth} - 3{,}0^{1)}\ \text{cm})}{2}$$

b) Calculate the maximum distance between the rods in position as follows:

$$L_{\max} = \frac{(\text{specified girth} - 3{,}0^{1)}\ \text{cm})}{2}$$

c) $$L_{\min} = \frac{C_{\min} - C_0}{2} = \frac{(2W - 3)}{2}$$

and

d) $$L_{\max} = \frac{C_{\max} - C_0}{2} = \frac{(G - 3)}{2}$$

Cycling extension

$$\Delta L = L_{\max} - L_{\min} = \frac{(G - 2W)}{2}$$

[1)] NOTE

See Figure B.7 for meaning of these symbols:

C_0 (zero setting girth) = $2d + \pi d$ = 3,05 cm rounded value = 3,0 cm

C_{min} (flat hose girth) = 2 W where W (flat width) is in centimetres

C_{max} (hose girth at practical elongation) = G where G is the girth from size table or indicated in centimetres

B.4.6 Zeroing of test apparatus prior to testing

B.4.6.1 Zero the force with the upper rods clamped in position (without test sample).

B.4.6.2 Zero the distance between the rods with upper and lower rods clamped in position. Consider the zero position to be when the rods are just touching (see Figure B.7)

B.4.7 Positioning of test sample

Position the rods to the calculated minimum distance L_{min}.

Remove the rods from the clamps and introduce them inside the hosiery and position the test sample onto the tensile tensometer.

To make up the correct stretch length direction either:

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

b) press the pins of the spacer bars onto the fabric along the marked lines across the hosiery, at intervals of the needles of approximately 10 mm.

The spacer bars have to be used where the top of the hosiery cannot be fixed to the parallelogram pins (D, F, G).

B.4.8 Tensile testing

Carry out the tensile test, stretching the test specimen continuously with a traverse rate of 200 mm/min five times, from the minimum distance L_{min} to the maximum distance L_{max} and return. Continue with a sixth extension to L_{max} and immediately record the force in cN when reaching L_{max}.

B.5 Calculation and expression of results

B.5.1 Practical elongation

$$EP(\%) = \frac{C_{\max} - C_{\min}}{C_{\min}} \times 100 = \frac{G - 2\mathrm{W}}{2\mathrm{W}} \times 100$$

B.5.2 Compression

The compression is calculated in accordance with the Laplace formula:

$$P_1 \text{ in hPa} = \frac{F_1 \times \Pi}{C_{\max} \times l} = 1{,}047 \frac{F_1}{C_{\max}}$$

where

P_1 = compression = force in fabric per hose length / leg girth in hPa

F_1 = 6th cycle load at L_{max} (2 x force in fabric) in cN

C_{max} is the hose circumference at L_{max} = girth in cm

l = centre rod length in cm

B.5.3 Residual pressure

The residual pressure (*RP*) is the compression at the measuring positions (other than B) expressed as a percentage of the compression at the ankle, the compression at the ankle being 100 %.

$$\mathrm{RP}(\%) = \frac{P'}{P_1} \times 100$$

where

P_1 is the compression at ankle

P' is the compression at any other measuring point other than the ankle

RP is the residual pressure expressed as a %

B.5.4 Stiffness

Determine the compression of the hosiery for the circumference cB-1 cm and for cB+1 cm. Indicate these pressures with P_{B-1} and $P_{B+1.}$ (see B.2.5).

The stiffness $S_1 = \frac{P_{B+1} - P_{B-1}}{2}$ hPa/cm and/or in mmHg/cm

B.5.5 Test report

The test report shall include at least 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 can also be expressed in millimetres of mercury (1 mmHg = 1,333 hPa).

f) Compression class.

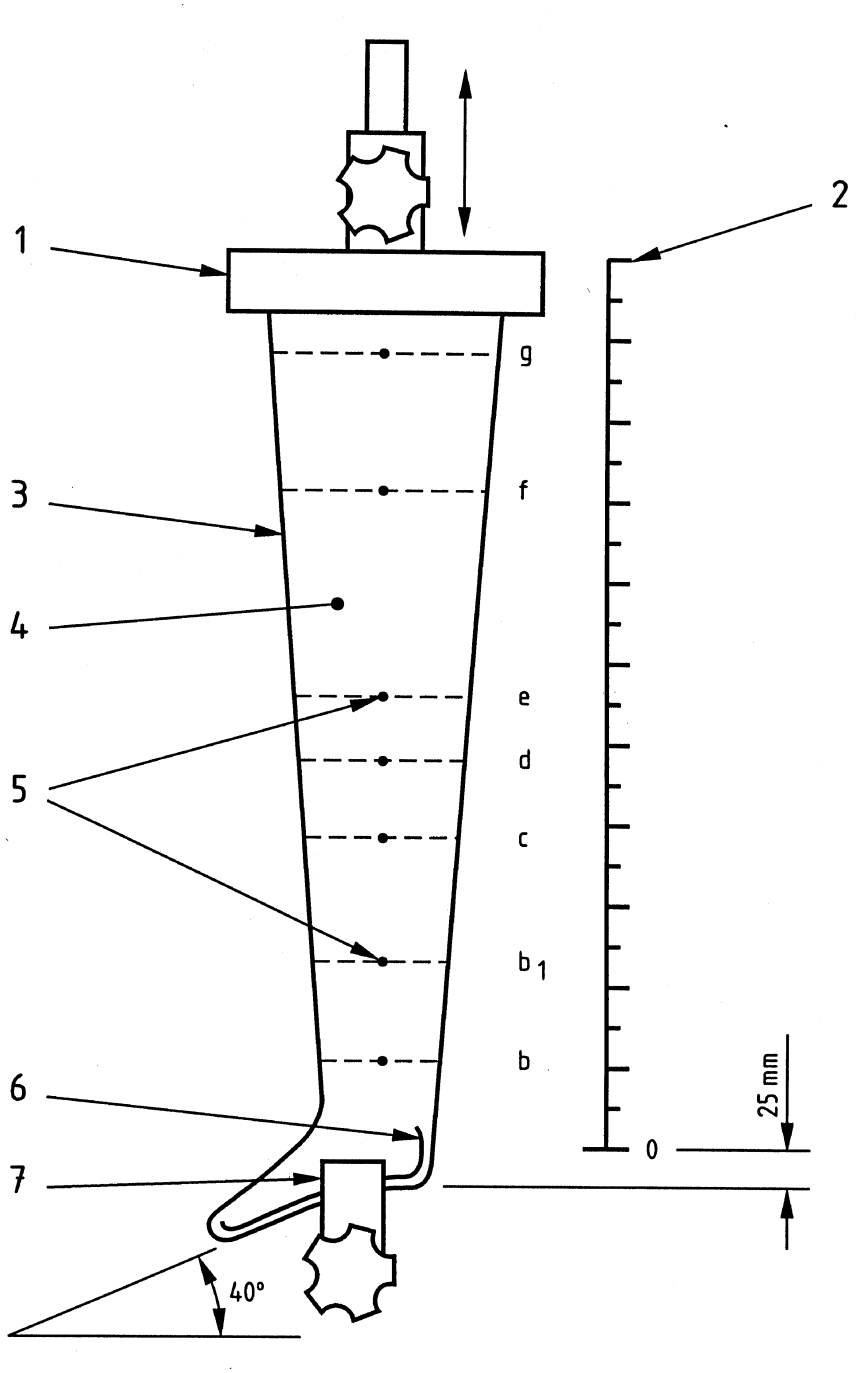
g) Residual pressure at all relevant measuring points and its correspondence with the limits specified in this European Prestandard.

h) Reference to this European Prestandard.

i) If appropriate, pressure profile.

j) If appropriate, stiffness at measuring point B.

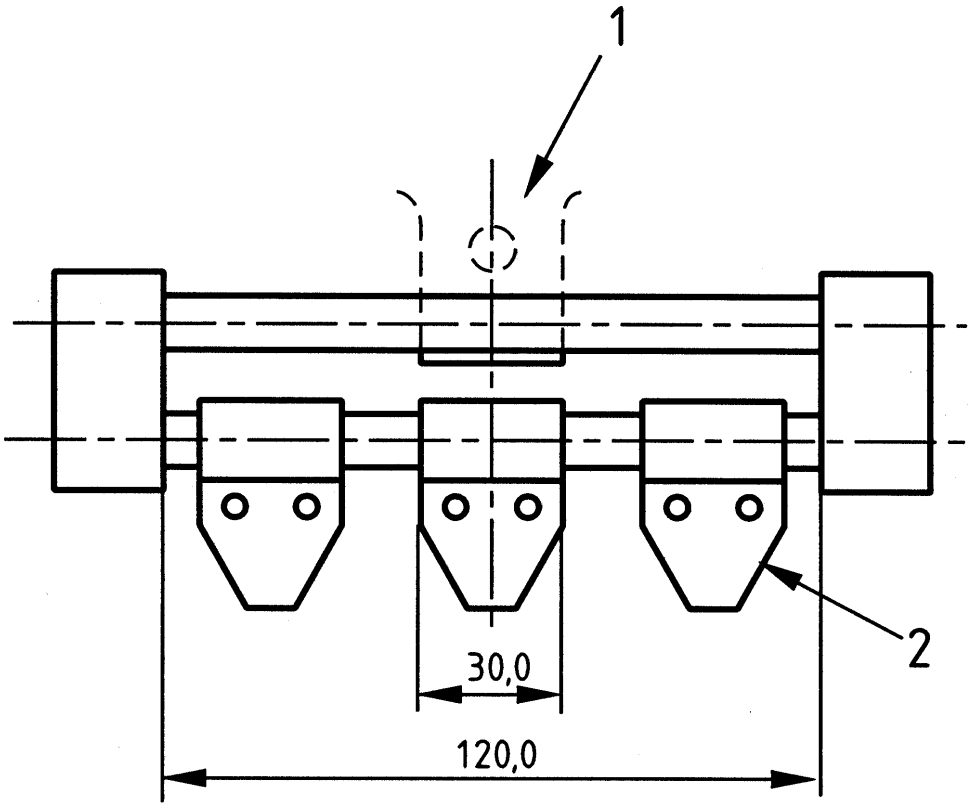
k) If appropriate, comparisons with the reference method.



Keys

1 Fastening by clamp or pins
2 Rule graduated in centimetres
3 Hosiery
4 Base board
5 Measuring points
6 Foot frame
7 Base clamp

Figure B.1 — Device for marking of measuring points — Example for flat-knitted hosiery



Keys

1 Clamp of marking board
2 Clamp to fit the hosiery

Figure B.2a) — Footclamp for round knitted hosiery

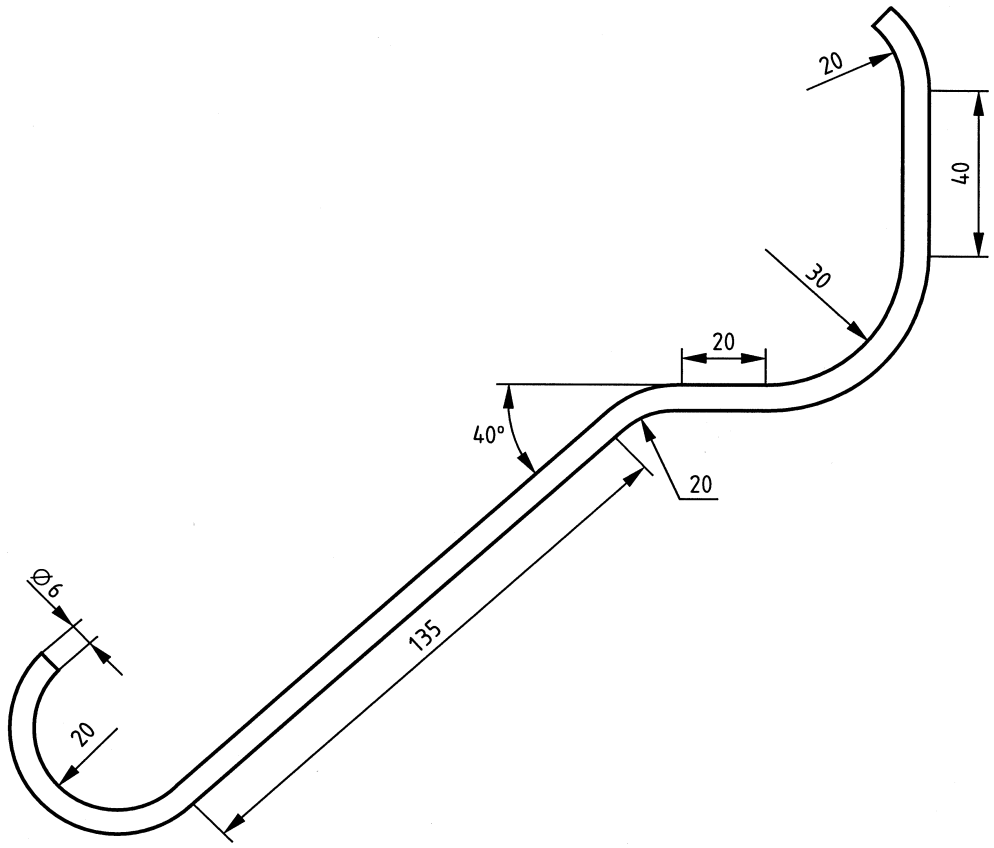
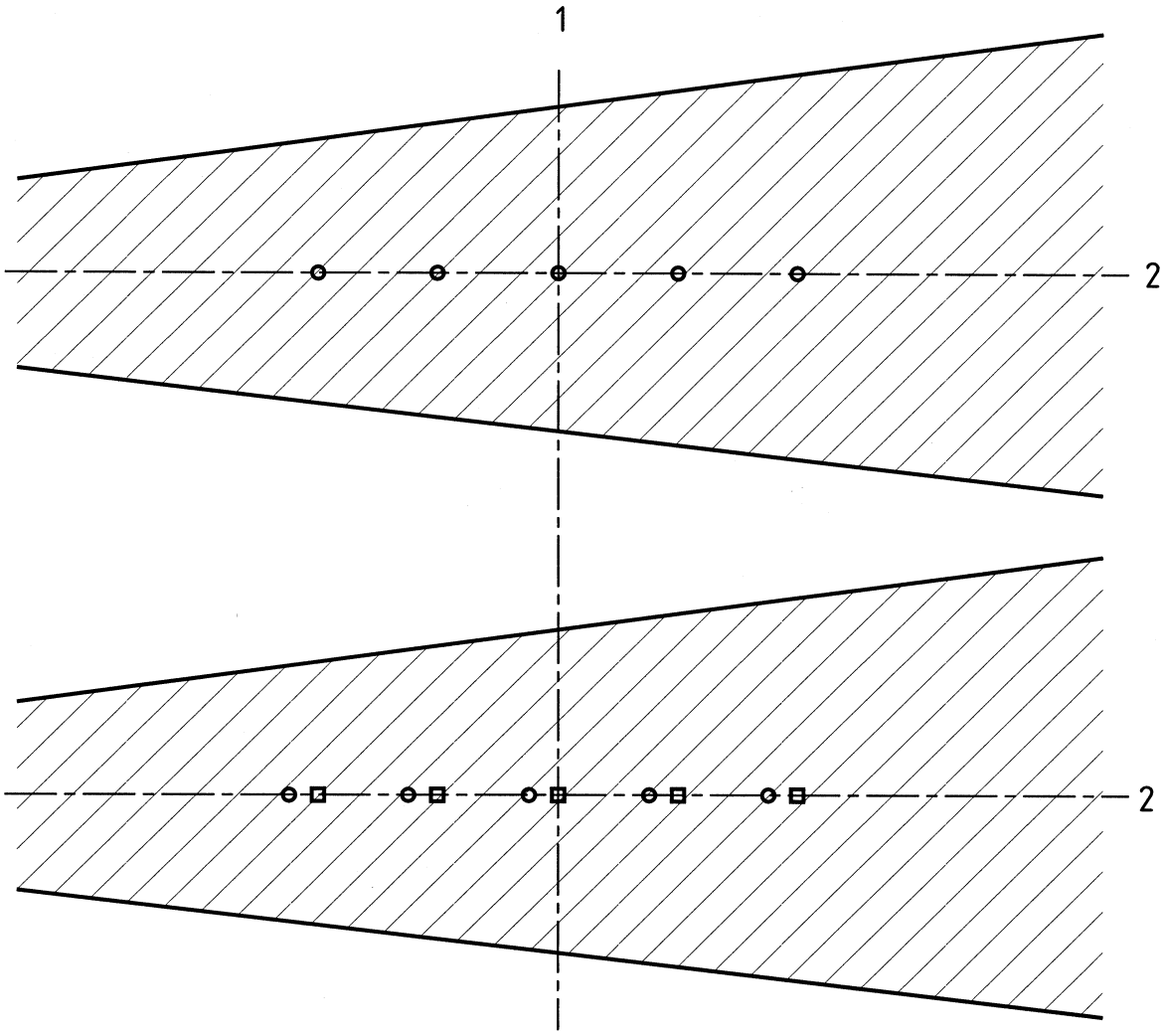


Figure B.2b) — Foot frame for flat knitted hosiery



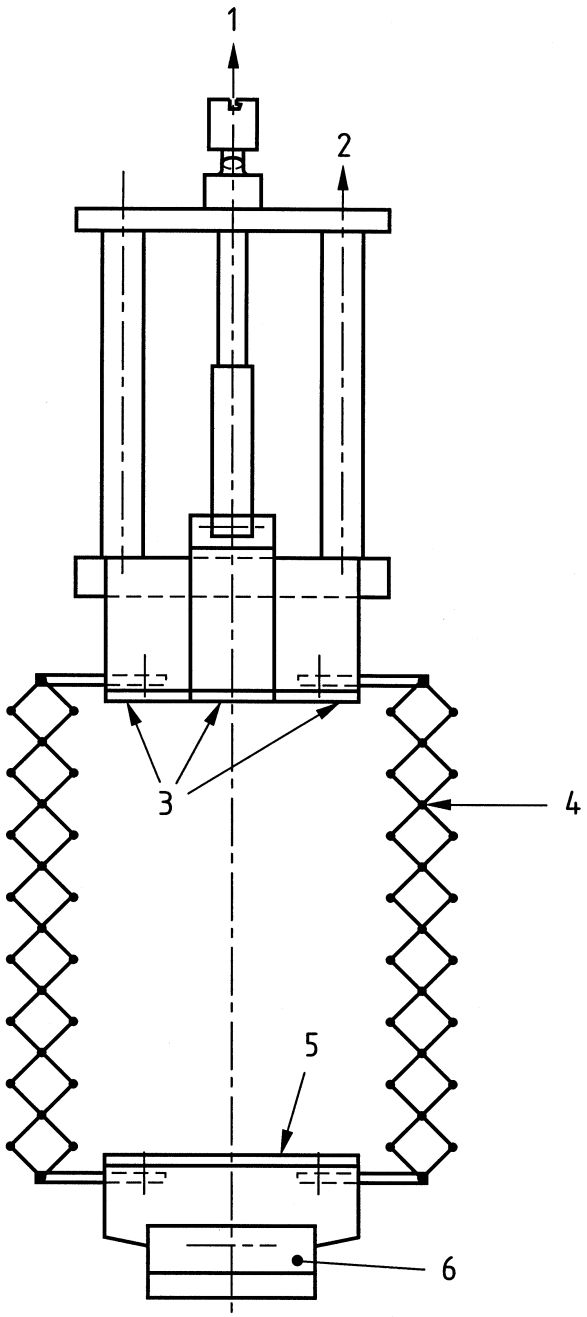
Keys

1 Measuring position
2 Centre line of hosiery

NOTE 1 Points marked along centre line of hosiery.

NOTE 2 Needle insertion points and stretcher pin lines referenced to the points marked along the centre line.

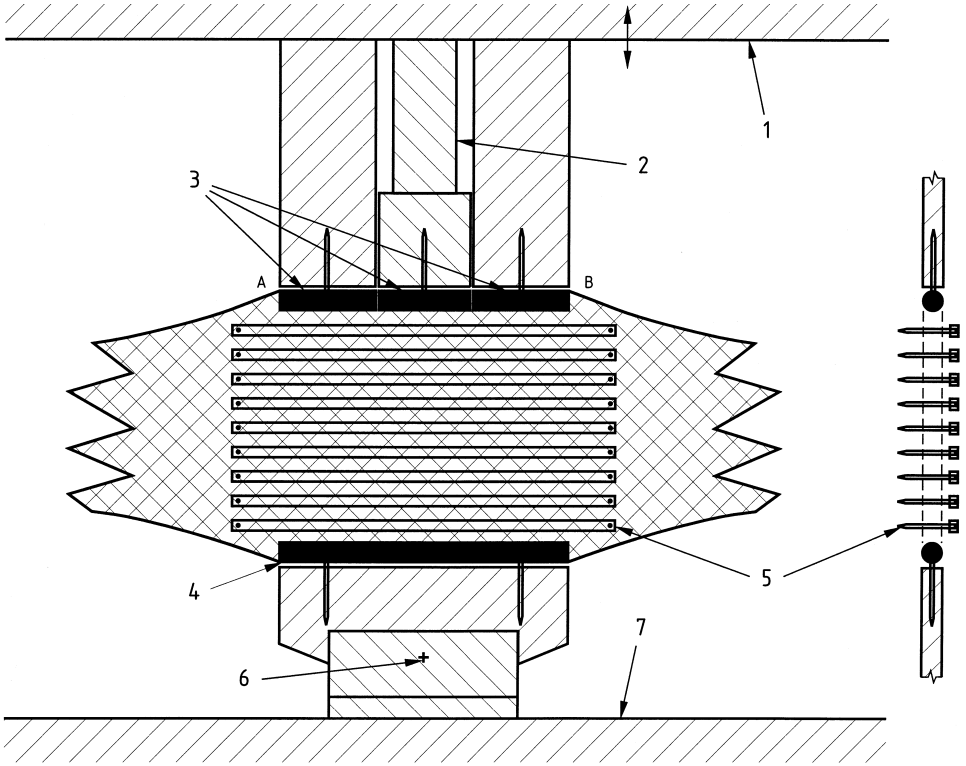
Figure B.2 — Marking of the measurement points



Keys

1 To force cells placed on the traverse
2 To the traverse
3 Needle rods (3)
4 Anti-necking spacers
5 Needle rod (1)
6 In the lower jaw

Figure B.3 — Compression measurement device



Keys

1 Traverse beam of tensile tester
2 Load cell
3 Upper needle rods
4 Lower needle rod
5 Anti-necking rods and pins
6 Pivot axis
7 Base of tensile tester

Figure B.4 — Schematic diagram of measurement device

Dimensions in millimetres

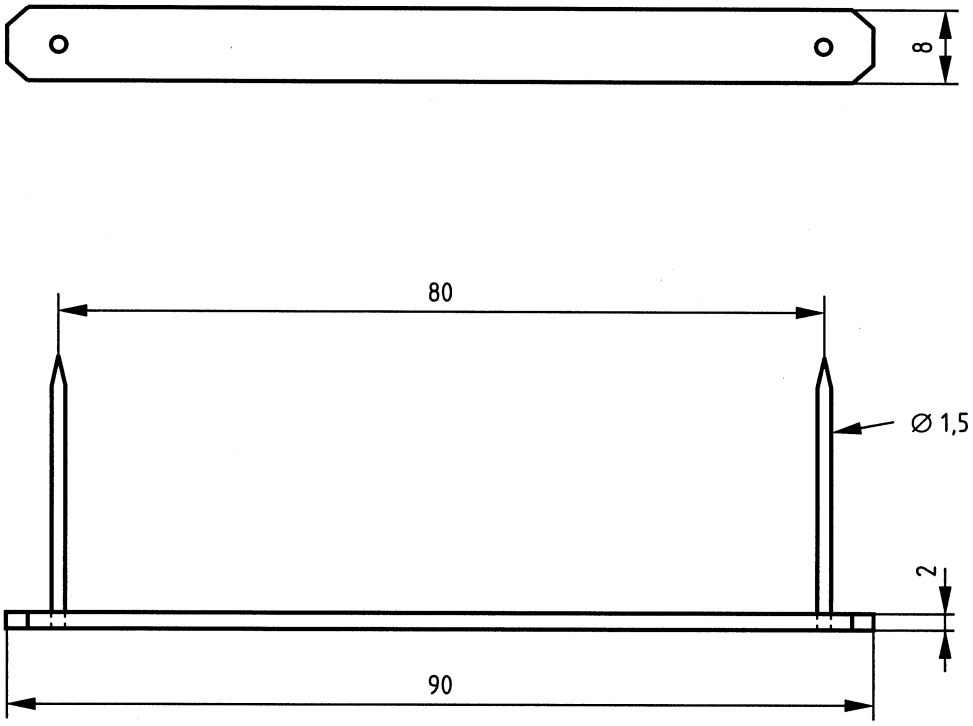


Figure B.5 — Anti-necking spacers

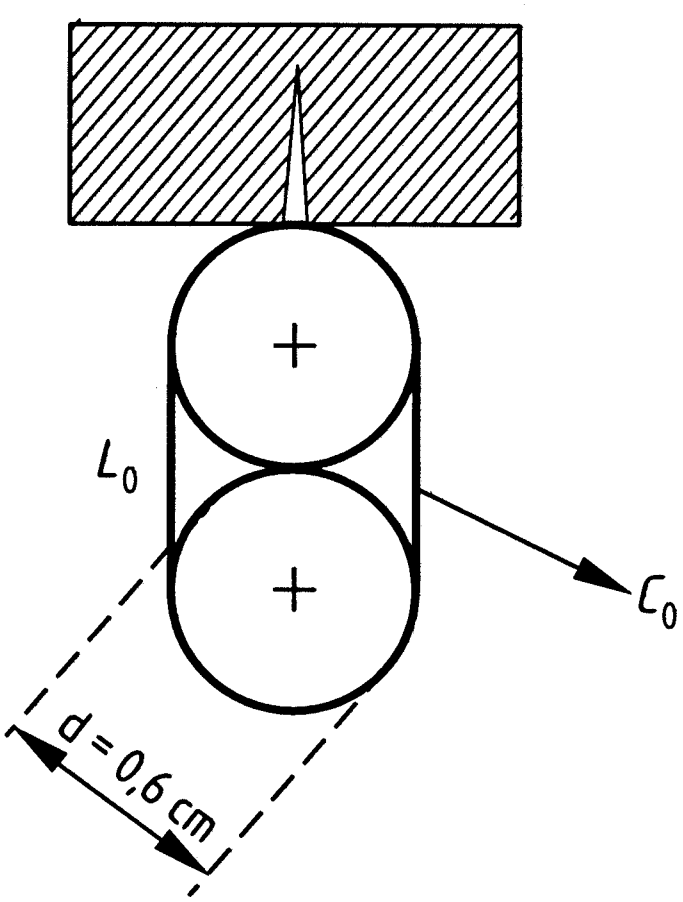


Figure B.7a) — Zero setting

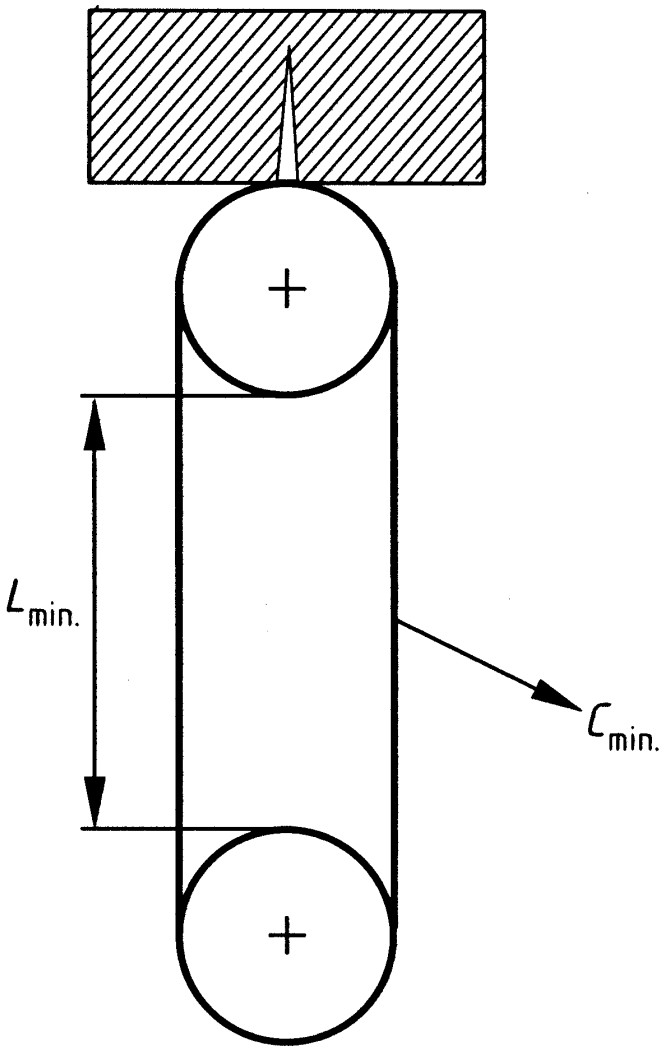


Figure B.7b) — Lower cycling limit

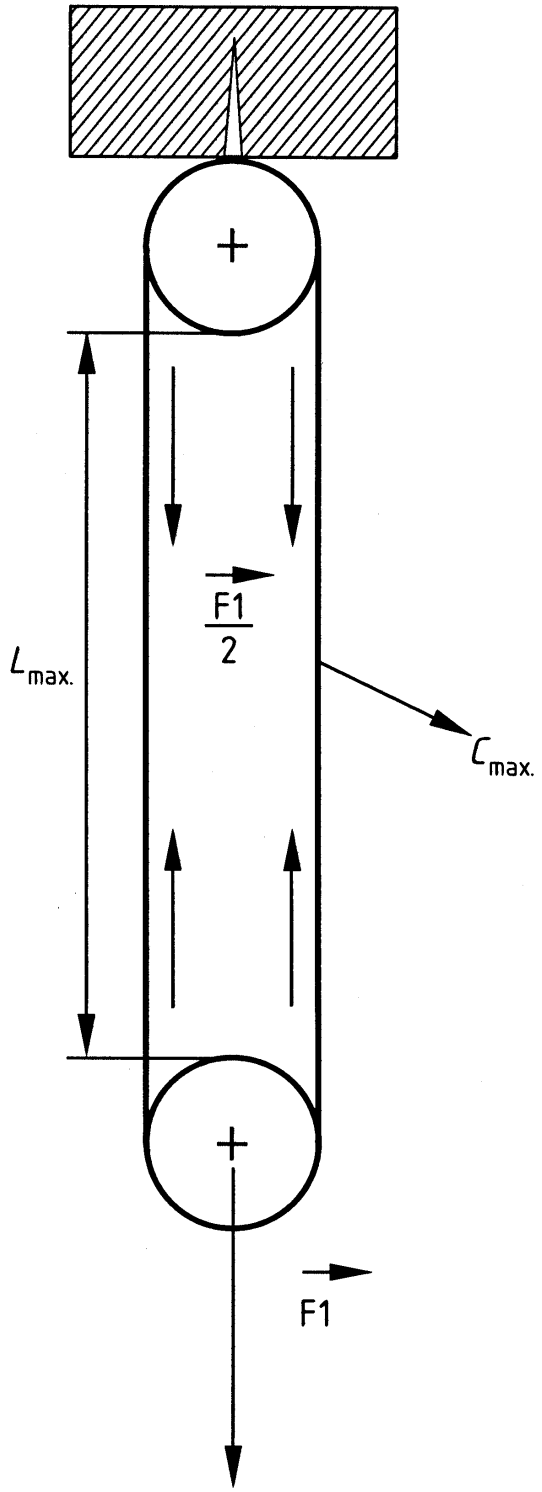


Figure B.7c) — Upper cycling limit

Figure B.6 — Minimum and maximum rod distances

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 100 mm 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 sets of "anti-necking spacers".

Apply a load of 5 daN to the test piece at a speed of 50 mm/min. Record the resulting length (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 length 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 Bonnigheim Germany
EMPA Eidgenossische Materialprufungs und – Forschungsanstalt	Lerchenfeldstrasse 5 CH - 9014 St. Gallen Switzerland
AFNOR	AFNOR Avenue Francis de Pressensé 11 F-93571 Saint Denis La Plaine Cedex France Centexbel Grotesteenweg Noord 2 B-9710 Gent (Zwijnaarde) Belgium
TNO	TNO Institute of Industrial Technology P.O. Box 6031 2600 JA DELFT The Netherlands
MST	MST Mark III (Medical Stocking Tester) Salzmann AG Salzmann MEDICO Unterstrasse 52 CH-9001 St Gallen Switzerland

Annex ZA
(informative)

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

This European Prestandard 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 concerning medical devices.

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

The following clauses for this prestandard (see Table ZA1) are likely to support requirements of Council Directive 93/42/EEC concerning medical devices.

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

Table ZA.1 — Correspondence between this European Prestandard and EU Directives

Clauses/sub-clauses of this European Prestandard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
1	1, 3	
4	1, 2, 3	
5	1, 2, 3	
6	1, 2, 3	
7	1, 2, 3	
8	1, 2, 3	
9	1, 2, 3	
10	1, 2, 3	
11	1, 2, 3, 5, 8.6	
12	1, 2, 3, 6	
12.1	13.1	
12.1 b)	13.3 b)	
12.1 c)	13.3 b)	
12.1 d)	13.6 b)	
12.1 e)	13.3, 13.3 b), 13.3 g)	
12.2	13.1, 13.6 a)	
12.2 a)	13.3 a), 13.1	
12.2 b)	13.3 b), 13.6 b)	
12.2 c)	13.3 a), 13.3 b)	
12.2 d)	13.6 b)	
12.2 e)	13.6 b)	
12.2 f)	13.3 b), 13.3 g)	
12.3	13.1, 13.6 a)	
12.3 a)	13.3 i), 13.6 h)	
12.3 b)	13.3 j), 13.3 k), 13.4, 13.6 h), 13.6 k)	
A2	7.1	
A3	7.1	
A4	7.1	
A5	7.1	
A6	7.1	
A7	7.1	
A8	7.1	
Annex B	1, 2, 3	
Annex C	1, 2, 3	
Annex D	1, 2, 3	

Bibliography

EN 20139:1992, *Textiles — Standard atmospheres for conditioning and testing (ISO 139:1973)*

ISO 1144, *Textiles — Universal system for designating linear density (Tex System)*

ISO 2321, *Rubber threads — Methods of test*

DD ENV 12718:2001

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