SLOVENSKI STANDARD
SIST ENV 12718:2002

01-maj-2002

Medicinske kompresijske nogavice

Medical compression hosiery

Medizinische Kompressionsstrümpfe

Bas médicaux de compression

Ta slovenski standard je istoveten z: **ENV 12718:2001**

ICS:

11.120.20	Sanitetni materiali, obveze in komprese	Wound dressings and compresses

SIST ENV 12718:2002 **en**

EUROPEAN PRESTANDARD

PRÉNORME EUROPÉENNE

EUROPÄISCHE VORNORM

ENV 12718

August 2001

ICS 11.120.20

English version

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Bas médicaux de compression

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

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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)

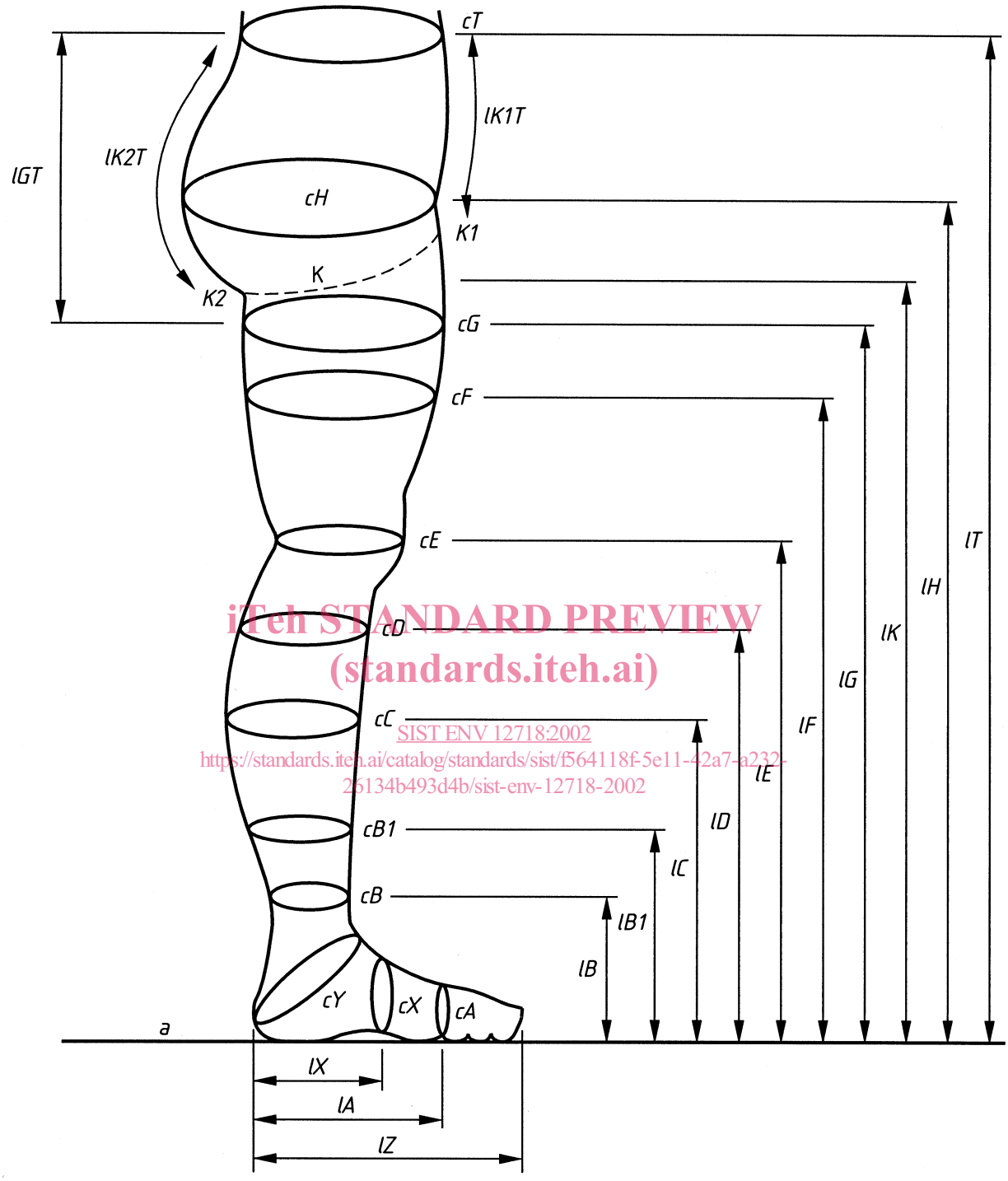
where

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
K2	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.