SLOVENSKI STANDARD
SIST ENV 12719:2002

01-maj-2002

Medicinske nogavice za prepreļ evanje tromboze

Medical thrombosis prophylaxis hosiery

Medizinische prophylaktische Antithrombosestrümpfe

Bas médicaux prophylaxiques anti-thromboses

Ta slovenski standard je istoveten z: **ENV 12719:2001**

ICS:

11.120.20	Sanitetni materiali, obveze in komprese	Wound dressings and compresses

SIST ENV 12719:2002 **en**

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ENV 12719

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ICS 11.120.20

English version

Medical thrombosis prophylaxis hosiery

Bas médicaux prophylaxiques anti-thromboses

Medizinische prophylaxische Antithrombosestrümpfe

This European Prestandard (ENV) was approved by CEN on 18 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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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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 A, B and C are normative and form part of this European Prestandard. Annexes 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.

1 Scope

This European Prestandard applies to medical thrombosis prophylaxis hosiery, knitted from threads made of natural fibres or synthetic fibres and elastic threads, which is used as a medical device for prophylaxis of venous thrombosis. The prestandard specifies requirements and test methods, except for custom-made hosiery.

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

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

EN 60456:1999, *Clothes washing machines for household use — Methods for measuring the performance (IEC 60456:1998, modified.)*

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
durability
ability of the hosiery to retain its designated compression properties

3.3
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

3.4
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

3.5
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

3.6
pressure profile
representation of the compression exerted by the hosiery along the leg

3.7
residual pressure
compression at a certain point expressed as a percentage of the compression at the ankle

3.8
standard size hosiery
hosiery manufactured in the types and sizes specified in this European Prestandard

3.9
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

3.10
medical thrombosis prophylaxis hosiery
hosiery which when worn on the leg exerts graduated compression on the leg surface and is principally intended to reduce the incidence of venous thrombosis in non-ambulant patients

NOTE Abbreviated in this prestandard to 'hosiery'.

4 Compression

The compression of the hosiery at the ankle shall be between 13 mmHg and 18 mmHg (respectively 17,5 hPa and 24 hPa). The compression at the ankle shall have a tolerance not exceeding ± 3 mmHg (4,0 hPa). The compression shall be measured in accordance with annex B.

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 Table 1 and Figure 1.

5.2 Measurement of length

If measured, length shall be measured and codes allocated in accordance with Table 2.

5.3 Measurement of girth

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

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 based on the ankle girth (cB).

5.4.1 Length

Length and range of lengths shall be chosen from Table 4.

5.4.2 Girth

Girths and range of girths shall be chosen from Table 5.

5.5 Designation of type and size of hosiery

5.5.1 Hosiery shall be designated by the type code according to Table 6 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 5;

— the range of girth at the upper end of the hosiery according to Table 5;

— the range of length according to Table 4.

Where values for intermediate measuring points fall in the same vertical column of Table 5 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 that package. The same applies in the figurative sense to the dimensions of the length given in Table 4.

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 13.

NOTE 2 A further example of type and size designation is AG 22-24 (52-64/70-75)

where

AG is the code for thigh hosiery;

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

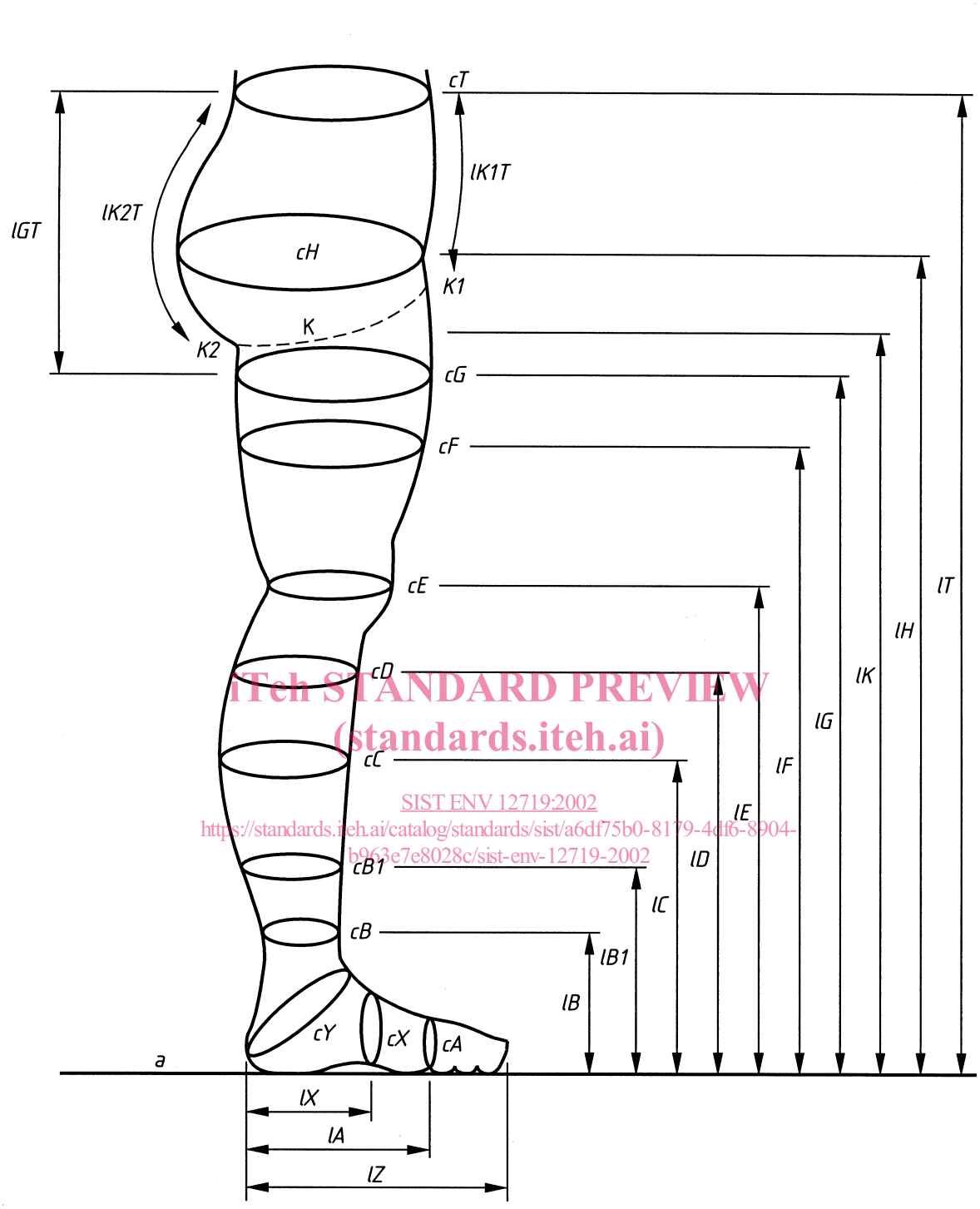
52-64 is the range of girth at the upper end of the hosiery (52 cm to 64 cm)

70-75 is the range of length (IG) (70 cm to 75 cm)

5.5.2 Alternatively a type code specified by the manufacturer shall be available on the hosiery. For this type code the range of dimensions of the leg that the hosiery is intended to fit shall be indicated on the package or leaflet, at least for the measurement points B,C and the upper end (D or G) and the length.

5.5.3 Hosiery intended for multi-patient use shall be optically size and type coded. The coding shall be wash-resistant (see annex A). The optical size and type code shall be easily identified.

NOTE The coding should be explained in or on the package (see 13.2).



NOTE Measurements should be preferably taken at the leg of the recumbent patient.

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

Table 1 — Nominal measuring points

Measuring point	Description of the measuring point
a	sole of the foot at the heel
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

Table 2 — Nominal measurement of length

Length code	Length of the leg
lB	distance measured from *a* to *B*
lBl	distance measured from *a* to *Bl*
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*