

Meditstiinilised survesukad ja -sokid

Medical compression hosiery

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-ENV 12718:2002 sisaldab Euroopa standardi ENV 12718:2001 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 18.09.2002 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-ENV 12718:2002 consists of the English text of the European standard ENV 12718:2001.</p> <p>This document is endorsed on 18.09.2002 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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<p>Käsitlusala:</p> <p>This 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.</p>	<p>Scope:</p> <p>This 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.</p>
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Võtmesõnad: bandages, medicine, orthopedics, packing, quality, quality assurance, sample surveys, size, size classification, specification (approval), specifications, stockings, surgical stockings, surveillance (approval), testing, trade marking, trade marks, vulcanized rubber

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.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



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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