EESTI STANDARD EVS-ENV 12719:2002

Meditsiinilised tromboosiprofülaktika sukad ja sokid

Medical thrombosis prophylaxis hosiery

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-ENV 12719:2002 sisaldab Euroopa standardi ENV 12719:2001 ingliskeelset teksti. Käesolev dokument on jõustatud 18.09.2002 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-ENV 12719:2002 consists of the English text of the European standard ENV 12719:2001. This document is endorsed on 18.09.2002 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This Standard applies to anti-thrombo embolism hosiery, knitted from threads made of natural fibres or synthetic fibres and elastic threads, which is used as a medical device for prophylaxis. The standard specifies performance requirements and test methods.	**Scope:** This Standard applies to anti-thrombo embolism hosiery, knitted from threads made of natural fibres or synthetic fibres and elastic threads, which is used as a medical device for prophylaxis. The standard specifies performance requirements and test methods.

ICS 11.120.20

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

EUROPEAN PRESTANDARD

PRÉNORME EUROPÉENNE

EUROPÄISCHE VORNORM

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.

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
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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