

**Reguleeritavad voodid puuetega inimestele.
Nõuded ja katsemeetodid**

Adjustable beds for disabled persons -
Requirements and test methods

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

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English version

Adjustable beds for disabled persons - Requirements and test methods

Lits réglables pour les personnes handicapées - Exigences et méthodes d'essai

Verstellbare Betten für behinderte Menschen - Anforderungen und Prüfverfahren

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 293 "Technical aids for disabled persons", the secretariat of which is held by SIS.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2000, and conflicting national standards shall be withdrawn at the latest by December 2000.

This European Standard 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 standard.

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

This standard provides one means to demonstrate that adjustable beds for disabled persons, which are also medical devices, conform to the essential requirements outlined in general terms in Annex 1 of the EU Directive 93/42/EEC. It is not intended to provide a means to show conformity with the requirements of any other directive.

There are three levels of European Standards dealing with technical aids for disabled persons. These are as follows, with level 1 being the highest:

- Level 1: General requirements for technical aids
- Level 2: Particular requirements for families of technical aids
- Level 3: Specific requirements for types of technical aids

Where standards for particular aids or groups of aids exist (level 2 or 3), the requirements of lower level standards take precedence over higher level standards. Therefore, to address all requirements for a particular aid, it is necessary to start with standards of the lowest available standard.

This is a combined level 2- and 3-standard (lowest possible) for adjustable beds for disabled persons, which are also medical devices, as specified in the scope.

Introduction

This standard is intended to apply to the most common products, but certain products will have to fulfil further or other requirements, e.g. regarding ergonomics, depending on the product in question. The risk analysis should be used for determining if further or other requirements should be addressed for each specific product.

Due to the dissimilarity of disabilities to be alleviated, it is not possible to specify requirements for adjustable beds for disabled persons in such a way that any bed of this type is covered. The present standard is therefore intended to cover the major part of adjustable beds for disabled persons. Certain beds, e.g. those designed to meet special needs, might need to fulfil other or further requirements, e.g. regarding ergonomics or EMC, than specified in this standard.

Beds covered by the present standard differ from beds covered by the IEC standard on electrically operated hospital beds, e. g. due the following characteristics:

- beds for disabled persons are intended to be used instead of domestic beds for permanent use, with the intention of alleviating or compensating for a disability or handicap and to facilitate better working conditions for attendants,
- beds for disabled persons do not require the same level of strength and cleaning as hospital beds, due to the different application,
- beds for disabled persons do not require the same electrical performance as hospital beds due to the different application.

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1 Scope

This standard specifies essential requirements and related test methods for non-electrically and electrically operated adjustable beds, including detachable bed boards, bed lifts, side rails, grab handles and lifting poles intended to be used by disabled persons to alleviate or compensate for a disability or handicap.

The standard also applies to stand up beds.

The standard does not apply to lateral tilt beds.

The standard does not apply to beds intended for use in the diagnosis, treatment or monitoring of patients under medical supervision (covered by EN 60601-2-38 for electrically operated hospital beds).

The standard does not apply to ordinary domestic beds, beds intended for children under 12 years of age, and mattresses.

The requirements in this standard do not take into account extreme heavy duty use of the bed.

2 Normative references

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

EN 1441	Medical devices - Risk analysis
EN 60529	Degrees of protection provided by enclosures (IP code) (IEC 60529:1989)
EN 60601-1	Medical electrical equipment - Part 1: General requirements for safety
EN 60601-1-2:1993	Medical electrical equipment - Part 1: General requirements for safety - 2: Collateral standard: Electromagnetic compatibility - Requirements and test methods
EN 61000-3-2	Electromagnetic compatibility (EMC) - Part 3: Limits - Section 2: Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
EN 61000-3-3	Electromagnetic compatibility (EMC) - Part 3: Limits - Section 3: Limitation of voltage fluctuation and flicker in low-voltage supply systems for equipment input current ≤ 16 A
EN 61000-4-3	Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques - Section 3: Radiated radio-frequency, electromagnetic field immunity test

- EN ISO 3746 Acoustics - Determination of sound power levels of noise sources using sound pressure - Survey method using an enveloping measurement surface over a reflecting plane (ISO 3746:1995)
- EN ISO 14253-1 Geometrical Product Specifications (GPS) - Inspection by measurement of workpieces and measuring equipment - Part 1: Decision rules for proving conformance or non-conformance with specifications (ISO 14253-1:1998)
- ISO 2439 Flexible cellular polymeric materials - Determination of hardness (indentation technique)
- GUM Guide to the Expression of Uncertainty in Measurement - GUM - 1st edition 1995 issued by BIPM, IEC, ISO, IUPAC, IUPAP, OIML - ISBN 92-67-10188-9

3 Terms and definitions

For the purposes of this standard the following terms and definitions apply:

3.1

Adjustable bed

Bed with one or more sections of the mattress support platform that can be adjusted in height and/or angle. The adjustment can be non-electrically or electrically operated.

NOTE: Whenever the term "bed" is used it comprises detachable bed boards, bed lifts and accessories.

3.2

Bed lift

Height adjustable undercarriages on which a standard bed can be mounted, thus serving as a height adjustable bed.

3.3

Stand up bed

Bed capable of raising the disabled person to a standing position.

3.4

Knock-down bed

Bed intended to be disassembled into few main parts for storage or transportation.

3.5

Safe working load (SWL)

Maximum permissible load (of disabled person, mattress, bed linen and accessories and those parts of the bed intended to be lifted by the bed lift) to operate the bed safely.

3.6

Grab handle

Supporting structure for the disabled when getting in and out of bed, and when turning from one side to the other in bed.

3.7

Side rail

Fold-away or removable rail intended to prevent the disabled to fall out of the bed.