

SLOVENSKI STANDARD SIST EN 1865-3:2012

01-oktober-2012

Nadomešča:

SIST EN 1865:2000

Oprema za ravnanje s pacienti v reševalnih vozilih - 3. del: Bolniška nosila za večje obremenitve

Patient handling equipment used in road ambulances - Part 3: Heavy duty stretcher

Krankentransportmittel im Krankenkraftwagen - Teil 3: Schwerlastkrankentrage

Equipements d'ambulances pour le transport des patients - Partie 3: Brancard

SIST EN 1865-3:2012

Ta slovenski standard/je_istoveten ziog/stanENs1865-3:20128-4d77-a7d6-

acb3ad2a7b29/sist-en-1865-3-2012

ICS:

11.160 Prva pomoč First aid

43.160 Vozila za posebne namene Special purpose vehicles

SIST EN 1865-3:2012 en,de

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EUROPEAN STANDARD

EN 1865-3

NORME EUROPÉENNE

EUROPÄISCHE NORM

June 2012

ICS 11.160

Supersedes EN 1865:1999

English Version

Patient handling equipment used in road ambulances - Part 3: Heavy duty stretcher

Spécifications d'équipements pour le transport de patient dans les ambulances routières - Partie 3: Brancard

Krankentransportmittel im Krankenkraftwagen - Teil 3: Schwerlastkrankentrage

This European Standard was approved by CEN on 10 May 2012.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions. The CTANDARD PREVIEW

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

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Foreword

This document (EN 1865-3:2012) has been prepared by Technical Committee CEN/TC 239 "Rescue systems", the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by December 2012, and conflicting national standards shall be withdrawn at the latest by December 2012.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document together with the EN 1865-1:2010, EN 1865-2:2010, EN 1865-4:2012 and EN 1865-5:2012 supersedes EN 1865:1999.

With respect to EN 1865:1999 the following changes were made:

- a) it shall be possible to increase the width of the lying part to minimum of 750 mm;
- b) the weight of the device was changed from 51 kg to maximum 65 kg;
- c) the capacity was changed from 150 kg to minimum 250 kg;
- d) the undercarriage, if power assisted, has no limits in height or in variable positions;
- e) the power source of the stretcher was defined;
- f) permanent deformation test of the frame shall be done with 400 kg instead of 250 kg and if the lateral extensions are fitted 75 kg shall be evenly set on each extension; 77-a7d6-
- g) permanent deformation test of the frame shall be done with 250 kg instead of 150 kg;
- h) splaying of the wheels test shall be done with 400 kg instead of 250 kg;
- the standard has been modified/integrated to meet the Medical Device Directive 93/42/EEC requirements
- j) the standard has been modified/integrated to comply with the Machinery Directive 2006/42/EC and its Essential Health and Safety Requirements (EHSRs).

This document 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.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

This European Standard is a part of EN 1865, *Patient handling equipment used in road ambulances*, which consists of the following parts:

- Part 1: General stretcher systems and patient handling equipment
- Part 2: Power assisted stretcher
- Part 3: Heavy duty stretcher
- Part 4: Foldable patient transfer chair
- Part 5: Stretcher support

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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Introduction

In this European Standard, reference is made to EN 1789, which specifies design requirements and test methods for road ambulances, which are relevant for checking requirements for such handling equipment.

1 Scope

This European Standard specifies minimum requirements for the design and performance of heavy duty stretchers used in road ambulances for the treatment and transportation of patients. It aims to ensure patient safety and minimize the physical effort required by staff operating the equipment.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 597-1, Furniture — Assessment of the ignitability of mattresses and upholstered bed bases — Part 1: Ignition source: Smouldering cigarette

EN 980, Symbols for use in the labelling of medical devices h.ai)

EN 1041, Information supplied by the manufacturer of medical devices

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EN 1789:2007+A1:2010, Medical vehicles and their equipment +- Road ambulances

EN 1865-1, Patient handling equipment used in road ambulances — Part 1: General stretcher systems and patient handling equipment

EN 60601-1-2, Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests (IEC 60601-1-2)

EN 62366, Medical devices — Application of usability engineering to medical devices (IEC 62366)

EN ISO 14971, Medical devices — Application of risk management to medical devices (ISO 14971)

3 Terms and definitions

For the purposes of this document, the following term and definition apply.

3.1

heavy duty stretcher

stretcher designed for the treatment and transportation of patients where the weight or dimensions of the patient exceed those of the operating capability of the main stretcher

Note 1 to entry: The term "main stretcher" is defined in EN 1865-1.

4 Requirements

4.1 General

Heavy duty stretchers shall be operated and maintained according to the instructions of the manufacturer. Risks shall be reduced to an acceptable level by using risk management principles in accordance with EN ISO 14971 in normal and single fault condition.

Heavy duty stretchers shall

- be manually or power operated;
- quarantee a safe and smooth operation;
- be free of sharp edges or deformation that could cause damage to persons or other equipment on board;
- have patient restraint-systems available; these restraint-systems shall have quick release systems;
- immobilize the patient, but at the same time shall permit treatment of the patient;
- ensure that the lying-sitting part is made of a strong material, which is bacterial resistant, fungal resistant, stain resistant, putrid resistant, easy to clean, washable and petrol-oil resistant.

The heavy duty stretcher shall be designed to transport patients with a weight that exceeds the load capacity of the main stretcher in EN 1865-Teh STANDARD PREVIEW

It shall be designed so that during loading and unloading the maximum burden on any personnel is half of the total weight of patient and stretcher and for the minimum possible time and in an optimal ergonomic position so that back bending is minimized.

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4.2 Dimensions

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Dimensions shall be measured from the outermost edges.

— Stretcher part: length: (1.950^{+20}_{-50}) mm

To accommodate tall patients it may be possible to increase the

length of the stretcher by a further 200 mm.

width: (550 ± 20) mm

It shall be possible to increase the width of the lying part to a

minimum of 750 mm.

height: maximum 300 mm from loading holding assembly to unloaded lying

part. This height dimension does not apply to stretchers with monoblock undercarriages. If a monoblock is not available, the stretcher shall be constructed such that it is detachable from the undercarriage. Where a stretcher support is used the measurement shall be taken from the top surface of the stretcher support to the

lying part of the stretcher.

 Undercarriage: length and width of the frame of the undercarriage when located in the ambulance shall not exceed length and width of the stretcher part.

4.3 Mass

— Stretcher part: 23 kg

Undercarriage including stretcher: 65 kg max. (combined weight)

NOTE In all cases the mass should be as low as possible.

4.4 Loading capacity

The loading capacity shall be a minimum of 250 kg.

4.5 Frame

4.5.1 General

The frame shall be in sturdy lightweight non twisting construction enabling use of cardiopulmonary resuscitation. All corners of the frame shall be radiused for greater safety.

It shall be possible to lock and secure the stretcher against lateral, longitudinal, vertical and oblique movements.

All mechanisms shall be constructed to prevent damage to the user and the patient.

4.5.2 Stretcher parts iTeh STANDARD PREVIEW

a) If side rails are mounted, they shall have a minimum length of 500 mm and a height between 150 mm and 200 mm measured from the top of the stretcher frame to the top of the side rail.

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- b) If longitudinal handles are incorporated they shall be fitted to the ends of the longitudinal frame such that they lock and do not twist when they are stowed or in use. They shall be designed to minimise the risk of injuries to the hands and wrists when being operated or the stretcher is carried at angles. It shall allow the fixation and use of a carrying harness.
- c) The stretcher shall have either a water and scratch resistant paint finish or be manufactured of corrosion resistant material. Both versions shall be unaffected by disinfectants.
- d) If intended to be used without undercarriage there shall be 4 wheels with a minimum diameter of 100 mm suitably placed to ensure stability.
- e) If intended to be used with undercarriage the stretcher shall be able to be fixed to the undercarriage without using supplementary means. A safe handling and lowering of the undercarriage shall be ensured.
- f) The fixed stretcher shall be easy to release from the stretcher fastener or the undercarriage.

NOTE There should be a facility to attach a support for infusion.

4.5.3 Undercarriage

- a) The undercarriage shall be fitted with 4 wheels with a diameter of at least 100 mm. At the foot end there shall be a minimum of two wheels that swivel 360 degrees and at least two wheels shall be fitted with a brake.
- b) The undercarriage shall be designed for loading and unloading at a maximum height of 750 mm.
- c) For manual undercarriages, these shall have a simple mechanism for height adjustment and shall have a minimum of 2 levels (car position and fully unfolded).