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English Version

Patient handling equipment used in ambulances - Part 6: Powered chairs

Spécifications d'équipements pour le transport de patient dans les ambulances routières - Partie 6 : Fauteuils à assistance électrique Krankentransportmittel im Krankenkraftwagen - Teil 6: Kraftunterstützte Krankenstühle

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 239.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (prEN 1865-6:2022) has been prepared by Technical Committee CEN/TC 239 "Rescue systems", the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

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

- Part 1: General stretcher systems and patient handling equipment; (forseen for revision)
- Part 2: Power assisted stretcher; (forseen for revision)
- Part 3: *Heavy duty stretcher; (forseen for revision)*
- Part 4: Foldable patient transfer chair; (forseen for revision)
- Part 5: Stretcher support; (forseen for revision)
- Part 6: Powered chairs. (the present document)

This document has been prepared under a Standardization Request given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s) / Regulation(s).

For relationship with EU Directive(s) / Regulation(s), see informative Annex ZA, which is an integral part of this document.

Scope 1

This document defines the minimum requirements for the design and performance of power assisted chairs, which are used for the conveyance of patients to and/or from road ambulances. It aims to ensure patient safety and to minimize the physical effort required by staff operating the equipment.

Normative references 2

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 597-1:2015, Furniture - Assessment of the ignitability of mattresses and upholstered bed bases - Part 1: *Ignition source smouldering cigarette*

EN ISO 20417:2021, Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)

EN 1865-1:2010+A1:2015, Patient handling equipment used in road ambulances - Part 1: General stretcher systems and patient handling equipment

prEN 1865-2:2022, Patient handling equipment used in ambulances — Part 2: Power assisted stretcher

EN 60601-1-2:2015, Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances— Requirements and tests (IEC 60601-1-2:2014 and A1:2020)

EN 62366-1:2015, Medical devices — Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015 and COR1:2016 and A1:2020)

EN ISO 14971:2019, Medical devices — Application of risk management to medical devices (ISO 14971:2019)

EN ISO 15223-1:2021, Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)

¹ Document impacted by A1:2021.

² Document impacted by AC:2015 and A1:2020.

³ Document impacted by A11:2021.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1

power assisted chair

device designed to transfer a patient in a sitting position to the road ambulance, but not to be used to transport a patient within the road ambulance

4 Requirements

4.1 General

These power assisted chairs shall be fitted with a powered mechanism to assist the descent and/or ascent of steps in order to minimize the need for manual transportation of the patient and chair.

When power assisted chairs are operated and maintained in accordance with manufacturer instructions, they should not present any high level of risk. Any identified risk shall be reduced to an acceptable level by using risk management principles in accordance with EN ISO 14971:2019 in normal and single fault condition.

The chair shall ensure that the operators are able to use the chair on stairs whilst maintaining good ergonomics and posture (e.g. by handles, bars).

All equipment for the handling of patients shall be free of any sharp edges or deformation that could cause injury to persons or damage to other equipment. The minimum radius should be 0,5 mm.

4.2 Dimensions

The dimensions of the power assisted chair in open position shall be as follows:

- The seat:
 - minimum height of 300 mm, measured from the ground;
 - maximum height of 550 mm, measured from the ground;
 - minimum width of 330 mm;
 - minimum depth of 350 mm;
- The backrest: minimum height of 395 mm, measured from the seat;
 - minimum width of 300 mm.

4.3 Mass

The total mass (excluding patient restraint) shall be not more than 32 kg.

The mass should be as low as possible.