



SLOVENSKI STANDARD
SIST EN 1865-3:2012/kFprA1:2014
01-september-2014

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

Equipement d'ambulances pour le transport de patients - Partie 3 : Brancard bariatrique

Ta slovenski standard je istoveten z: EN 1865-3:2012/FprA1

ICS:

11.160	Prva pomoč	First aid
43.160	Vozila za posebne namene	Special purpose vehicles

SIST EN 1865-3:2012/kFprA1:2014 **en,fr,de**

EUROPEAN STANDARD
NORME EUROPÉENNE
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FINAL DRAFT
EN 1865-3:2012

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ICS 11.160

English Version

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

Équipement d'ambulances pour le transport de patients -
Partie 3 : Brancard bariatrique

Krankentransportmittel im Krankenkraftwagen - Teil 3:
Schwerlastkrankentrage

This draft amendment is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 239.

This draft amendment A1, if approved, will modify the European Standard EN 1865-3:2012. If this draft becomes an amendment, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration.

This draft amendment was established by CEN 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.

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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: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN 1865-3:2012/FprA1:2014) 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 Unique Acceptance Procedure.

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(s).

Note: Due to fact that the Framework Partnership Agreement between the Commission and CEN & CENELEC is not signed yet, there are currently no New Approach Consultants in place for 2014. Therefore the provisions of CEN-CENELEC Guide 15 cannot be met.

This shall not prevent the processing of draft standards nor the offering of harmonized standards to the Commission. In particular, draft standards can be sent to vote without Consultant assessment.

This note will be removed from the Foreword of the finalized publication.

EN 1865-3:2012/FprA1:2014 (E)**1 Modification to the Introduction**

Replace "EN 1789" with "EN 1789:2007+A1:2010".

2 Modifications to Clause 2, Normative References

Replace "EN 597-1" with "EN 597-1:1994".

Delete:

"EN 980, *Symbols for use in the labelling of medical devices*".

Replace "EN 1041" with "EN 1041:2008".

Replace "EN 1865-1" with "EN 1865-1:2010".

Replace the whole reference to "EN 60601-1-2" with the following one:

"EN 60601-1-2:2007, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests (IEC 60601-1-2:2007, modified)*".

Replace the whole reference to "EN 62366" with the following one:

"EN 62366:2008, *Medical devices — Application of usability engineering to medical devices (IEC 62366:2007)*".

Replace the whole reference to "EN ISO 14971" with the following one:

"EN ISO 14971:2012, *Medical devices — Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)*".

Add at the very end of the list:

"EN ISO 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements (ISO 15223-1:2012)*".

3 Modification to Clause 3, Terms and definitions

In Definition 3.1, in Note 1 to entry, replace "EN 1865-1" with "EN 1865-1:2010".

4 Modifications to 4.1, General

In the 1st paragraph, replace "EN ISO 14971" with "EN ISO 14971:2012".

In the 3rd paragraph, replace "EN 1865-1" with "EN 1865-1:2010".

5 Modifications to 4.2, Dimensions

In the list, replace " $(1\ 950_{-50}^{+20})$ " with " $(1\ 950_{-50}^{+120})$ ".

In the list, replace " (550 ± 20) mm" with " $(550 \pm_{-20}^{+60})$ mm".

6 Modification to 4.3, Mass

In the list, replace "65 kg" with "80 kg".

7 Modification to 4.5.4, Power source

In List Entry c), replace "EN 60601-1-2" with "EN 60601-1-2:2007" and replace "EN 62366" with "EN 62366:2008".

8 Modification to 4.7, Flammability – toxicity burning gases

Replace "EN 597-1" with "EN 597-1:1994".

9 Modification to Clause 6, Marking

Replace "EN 980" with "EN ISO 15223-1:2012" and replace "EN 1041" with "EN 1041:2008".

10 Modification to Annex ZA (informative), Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices

In Table ZA.2, replace four times "EN ISO 14971" with "EN ISO 14971:2012".