SLOVENSKI STANDARD
SIST EN 1865-2:2010/kFprA1:2014

01-september-2014

Oprema za ravnanje s pacienti v reševalnih vozilih - 2. del: Nosila s pomožnim pogonom

Patient handling equipment used in road ambulances - Part 2: Power assisted stretcher

Krankentransportmittel im Krankenkraftwagen - Teil 2: Kraftunterstützte Krankentrage

Spécifications d'équipements pour le transport de patient dans les ambulances routières - Partie 2: Brancard motorisé

Ta slovenski standard je istoveten z: **EN 1865-2:2010/FprA1**

ICS:

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

SIST EN 1865-2:2010/kFprA1:2014 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

FINAL DRAFT
EN 1865-2:2010

FprA1

June 2014

ICS 11.160

English Version

Patient handling equipment used in road ambulances - Part 2: Power assisted stretcher

Spécifications d'équipements pour le transport de patient dans les ambulances routières - Partie 2: Brancard motorisé

Krankentransportmittel im Krankenkraftwagen - Teil 2: Kraftunterstützte Krankentrage

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 1865-2:2010. 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 1865-2:2010/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.

1 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 "EN 60601-1-2" *with* "EN 60601-1-2:2007".

Replace "EN 62366" *with* "EN 62366:2008".

Replace "EN ISO 14971" *with* "EN ISO 14971:2012".

Add the following reference at the 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)*".

2 Modification to 4.1, General

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

3 Modifications to 4.2.2, Dimensions

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

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

4 Modification to 4.2.3, Mass

In the list, replace "65 kg" *with* "75 kg".

5 Modification to 4.2.6, 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".

6 Modification to 4.2.8, Restraint system

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

7 Modification to 4.2.9, Flammability – Toxicity burning gases

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

8 Modification to Clause 5, Marking

Replace "EN 980" *with* "EN ISO 15223-1:2012".

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

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

Replace the whole Annex ZA with the following one:

"

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices and of EU Directive 2006/42/EC on Essential Health and Safety Requirements

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on Medical Devices and of the New Approach Directive 2006/42/EEC on Essential Health and Safety Requirements.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Tables ZA.1 and ZA.2 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on Medical Devices

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
Clause 4, all subclauses	7.1, first and second indents	Toxicity is not covered
4.1, 4.2.5, 4.2.7	7.3, first part only	
Clause 4, all subclauses	8.1	
Clause 4, all subclauses	9.2, first indent	Covered for physical, dimensional and ergonomic features
4.2.9	9.3	
4.2.6	12.2	
Clause 4, all subclauses	12.7.1	