SLOVENSKI STANDARD
SIST EN 1865-1:2010/kFprA1:2014

01-december-2014

Specifikacija za opremo za ravnanje s pacienti v reševalnih vozilih - 1. del: Specifikacija za splošne sisteme nosil in opremo za ravnanje s pacienti

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

Krankentransportmittel im Krankenkraftwagen - Teil 1: Allgemeine Krankentragesysteme und Krankentransportmittel

Spécifications d'équipements pour le transport de patient dans les ambulances routières - Partie 1: Systèmes généraux de brancards et équipement pour le transport de patients

Ta slovenski standard je istoveten z: **EN 1865-1:2010/FprA1**

ICS:

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

SIST EN 1865-1:2010/kFprA1:2014 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

FINAL DRAFT
EN 1865-1:2010

FprA1

September 2014

ICS 11.160; 43.160

English Version

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

Spécifications d'équipements pour le transport de patient dans les ambulances routières - Partie 1: Systèmes généraux de brancards et équipement pour le transport de patients

Krankentransportmittel im Krankenkraftwagen - Teil 1: Allgemeine Krankentragesysteme und Krankentransportmittel

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 1865-1:2010. 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.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

Foreword

This document (EN 1865-1:2010/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).

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

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 Modification to the Introduction

In the last paragraph before the note, replace "EN 1789" *with* "EN 1789:2007+A2:2014".

2 Modification to Clause 2, Normative references

Replace

"EN 980, *Symbols for use in the labelling of medical devices*" *with* "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)*";

Replace

"EN 597-1" *with* "EN 597-1:1994";

"EN 1041" *with* "EN 1041:2008+A1:2013";

"prEN 1021-1" *with* "EN 1021-1:2014";

"EN 1789:2007+A1:2010" *with* "EN 1789:2007+A2:2014";

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

3 Modification to Clause 4, Requirements

In 4.1, first paragraph, replace "EN ISO 14971" *with* "EN ISO 14971:2012".

In 4.2.8, replace "EN 597-1" *with* "EN 597-1:1994".

In 4.2.10, first sentence, replace "EN 1789:2007+A1:2010" *with* " EN 1789:2007+A2:2014".

In 4.3.7, replace "EN 1021-1" *with* "EN 1021-1:2014".

In 4.4.7, replace "EN 597-1" *with* "EN 597-1:1994".

In 4.5.7, replace "EN 597-1" *with* "EN 597-1:1994".

In 4.6.7, replace "EN 597-1" *with* "EN 597-1:1994".

In 4.7.6, first paragraph, replace "EN 1789:2007+A1:2010" *with* " EN 1789:2007+A2:2014".

In 4.7.7, replace "EN 597-1" *with* "EN 597-1:1994".

In 4.8.7, replace "EN 597-1" *with* "EN 597-1:1994".

In 4.9.7, replace "EN 1021-1" *with* "EN 1021-1:2014".

In 4.10.7, replace "EN 1021-1" *with* "EN 1021-1:2014".

In 4.10.9, replace "EN 1789:2007+A1:2010" *with* " EN 1789:2007+A2:2014".

4 Modification to Clause 5, Test methods

In 5.1.2, replace "EN 1789:2007+A1:2010" *with* " EN 1789:2007+A2:2014".

5 Modification to Clause 6, Marking

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

Replace "EN 1041" *with* "EN 1041:2008+A1:2013".

6 Modification to Annex ZA

Replace Annex ZA with the following:

"

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC concerning Medical Devices

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 EU Directive 93/42/EEC.

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 normative clauses of this standard confers, within the limits of the scope of this standard, a presumption of conformity with the relevant Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 lays out which clauses of this standard are likely to support the relevant requirements of Directive 93/42/EEC.

Compliance with these clauses of this standard provides one means of conforming with the specific Essential Requirements of the Directive concerned and associated EFTA regulations.

Table ZA — Relationship between this 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
4.1, 4.2.5, 4.2.6, 4.2.8, 4.3.4, 4.3.5, 4.3.7, 4.4.5, 4.4.7, 4.5.5, 4.5.7, 4.6.4, 4.6.5, 4.6.7, 4.7.1, 4.7.7, 4.8.5, 4.8.7, 4.9.4, 4.9.5, 4.9.7, 4.10.4, 4.10.5, 4.10.7	7.1, first and second indents	Toxicity is not covered.
4.1, 4.2.5, 4.2.6, 4.3.5, 4.4.5, 4.5.5, 4.6.5, 4.7.1, 4.8.5, 4.9.5, 4.10.5	7.3, first part	
4.1, 4.2.6, 4.3.5, 4.4.5, 4.5.5, 4.6.5, 4.7.1, 4.8.5, 4.9.5, 4.10.5	8.1	
4 (all subclauses), 5 (all subclauses)	9.2, first indent	
4.2.8, 4.3.7, 4.4.7, 4.5.7, 4.6.7, 4.7.7, 4.8.7, 4.9.7, 4.10.7	9.3	
4 (all subclauses), 5 (all subclauses)	12.7.1	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard."