SLOVENSKI STANDARD
SIST EN 1789:2007+A1:2010/kFprA2:2014

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Medicinska vozila in pripadajoča oprema - Reševalna vozila

Medical vehicles and their equipment - Road ambulances

Rettungsdienstfahrzeuge und deren Ausrüstung - Krankenkraftwagen

Véhicules de transport sanitaire et leurs équipements - Ambulances routières

Ta slovenski standard je istoveten z: **EN 1789:2007+A1:2010/FprA2**

ICS:

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

SIST EN 1789:2007+A1:2010/kFprA2:2014 **en,fr,de**

EUROPEAN STANDARD

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FINAL DRAFT
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ICS 11.160; 43.160

English Version

Medical vehicles and their equipment - Road ambulances

Véhicules de transport sanitaire et leurs équipements - Ambulances routières

Rettungsdienstfahrzeuge und deren Ausrüstung - Krankenkraftwagen

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 A2, if approved, will modify the European Standard EN 1789:2007+A1:2010. 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.

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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

Contents

Foreword

This document (EN 1789:2007+A1:2010/FprA2:2014) 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.

1 Modification to the Foreword

Delete the old Foreword and replace with new Foreword (not tagged).

2 Addition of an Introduction

Add an Introduction with the following text and footnote:

"

Introduction

In the development of the European standard EN during the 90's, Directive 70/156/EEC has been considered.

In October 2009, CEN/TC 239 appointed an ad-hoc group to evaluate the impact of the Directive 2007/46/EC which replaces Directive 70/156/EEC, on EN 1789:2007 and to assess its application in different member countries of CEN.

Moreover the definition of ambulance of the COMMISSION REGULATION (EU) No 678/2011 (14 July 2011 replacing Annex II and amending Annexes IV, IX and XI to Directive 2007/46/EC) refers to EN 1789:2007.

The appointed ad-hoc group reported its findings as follows:

— EN 1789:2007 has not been applied consistently by notified bodies since the text for verifying compliance is open to interpretation and may cause difficulties to Technical Services (TS) as defined in Directive 2007/46/EC, EN 1789:2007 or local authorities.

— these differences can lead to declarations that the same ambulance complies or does not comply with EN 1789:2007;

— manufacturers of ambulances may have the same problems of interpretation in the design of their ambulances;

— users of ambulances may have the same problems of interpretation that affects their responsibility.

This second amendment[1)] gives an answer to questions concerning the application of EN 1789:2007 and avoids differences in interpretation between such notified bodies to check compliance of vehicles specially adapted to medical transportation (Road ambulances).

NOTE Such as the demonstration of compliance to the requirements of 4.5.9 or 4.3.".

3 Modifications to Clause 2, Normative References

Delete the following normative references:

"EN 739, *Low-pressure hose assemblies for use with medical gases*";

"EN 980, *Graphical symbols for use in the labelling of medical devices*";

"EN ISO 9919, *Medical electrical equipment — Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use (ISO 9919:2005)*";

"EN ISO 21647, *Medical electrical equipment — Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 21647:2004)*";

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1) "The first amendment published in 2010 only updates Table ZA.1 to consider the revision of Directive 93/42/EEC.".

"IEC 60364-7-708, *Electrical installations of buildings — Part 7: Requirements for special installations or locations. Section 708 — Electrical installations in caravan parks and caravans*[1)]", *delete corresponding footnote.*

ISO 3795, *Road vehicles, and tractors and machinery for agriculture and forestry — Determination of burning behaviour of interior materials*"

Replace

"EN 1865, *Specifications for stretchers and other patient handling equipment used in road ambulances*" *with* "EN 1865-1:2010, *Patient handling equipment used in road ambulances — Part 1: General stretcher systems and patient handling equipment*";

"EN 60068-2-6, *Environmental testing — Part 2: Tests — Tests Fc: Vibration (sinusoidal) (IEC 60068-2-6:1995 + Corrigendum 1995)*" *with* "EN 60068-2-6, *Environmental testing — Part 2-6: Tests — Tests Fc: Vibration (sinusoidal) (IEC 60068-2-6:2007)*";

"EN 60601-2-4, *Medical electrical equipment — Part 2-4: Particular requirements for the safety of cardiac defibrillators (IEC 60601-2-4:2002)*" *with* "EN 60601-2-4:2011, *Medical electrical equipment — Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators (IEC 60601-2-4:2010)*"

and

"EN 60068-2-64, *Environmental testing — Part 2: Test methods — Test Fh: Vibration, broad-band random (digital control) and guidance (IEC 60068-2-64:1993 + Corrigendum 1993)*" with "EN 60068-2-64:2008, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance (IEC 60068-2-64:2008)*";

Add the following normative references:

"EN 1865-2:2010, *Patient handling equipment used in road ambulances — Part 2: Power assisted stretcher*

EN 1865-4:2012, *Patient handling equipment used in road ambulances — Part 4: Foldable patient transfer chair*

EN 1865-5:2012, *Patient handling equipment used in road ambulances — Stretcher support*";

"EN 13501-1:2009, *Fire classification of construction products and building elements — Part 1: Classification using test data from reaction to fire tests*";

"EN ISO 5359:2008, *Low-pressure hose assemblies for use with medical gases (ISO 5359:2008)*";

"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)*";

"EN ISO 80601-2-61:2011, *Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO 80601-2-61:2011)*";

"EN ISO 80601-2-55:2011, *Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 80601-2-55:2011)*";

"IEC 60364-7-721:2007, *Low-voltage electrical installations — Part 7-721: Requirements for special installations or locations — Electrical installations in caravans and motor caravans (IEC 60364-7-721:2007-04)*".

Replace

"EN 3-7" *with* "EN 3-7:2004+A1:2007";

"EN 420" *with* "EN 420:2003+A1:2009";

"EN 455-1" *with* "EN 455-1:2000";

"EN 455-2" *with* "EN 455-2:2009+A2:2013";

"EN 794-3" *with* "EN 794-3:1998+A1:2009";

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

"EN 12470-1" *with* "EN 12470-1:2000+A1:2009";

"EN 13544-1" *with* "EN 13544-1:2007+A1:2009";

"EN 60068-2-29" *with* "EN 60068-2-29:1993";

"prEN ISO 15002" *with* "EN ISO 15002:2008" *and in the title replace* "*(ISO/DIS 15002:2006)*" *with* "*(ISO 15002:2008)*";

"EN ISO 407" *with* "EN ISO 407:2004";

"EN ISO 10524-1" *with* "EN ISO 10524-1:2006";

"EN ISO 10524-3" *with* "EN ISO 10524-3:2006";

"EN ISO 14971" *with* "EN ISO 14971:2012" *and in the title replace* "*(ISO 14971:2007)*" with "*(ISO 14971:2007, Corrected version 2007-10-01)*";

"EN ISO 19054" *with* "EN ISO 19054:2006";

"EN ISO 20345" *with* "EN ISO 20345:2011" *and in the title replace* "*(ISO 20345:2004)*" *with* "*(ISO 20345:2011)*".

4 Modifications to Clause 3, Terms and definitions

In 3.3, footnote 2, replace "Directive 70/156" *with* "Directive 2007/46/EEC".

In 3.4, delete "unloaded mass" *and* "vehicle".

Replace 3.5 with the following:

"**3.5**
ambulance loading capacity
difference between the permissible gross vehicle mass and the mass according to 92/21/EEC modified of the road ambulance including the driver taken as 75 kg and all fixed installations, mass reserve according to 4.5.10 and all passengers

Note 1 to entry: This represents the mass that may be distributed on the road ambulance such that the permissible axle loads are not exceeded."

Delete 3.6 loading capacity and update numbering.

Add the following new terms and definitions:

"**3.8**
Technical Service (TS)
body authorized according to directive 2007/46/EEC to decide the conformity of the ambulance as a road vehicle

3.9
means of verification (MoV)
deliverables or tests to be performed to allow the technical service to establish the compliance of the ambulance to EN 1789:2007 in the context of the vehicle type approval

3.10
non equipped ambulance
ambulance without any equipment as listed in Table 9 to Table 19

Note 1 to entry: Stretcher support as defined in EN 1865-5:2012 is included in the non-equipped ambulance.".

5 Modifications to Clause 4, Requirements

In 4.1.1, delete the first paragraph.

In 4.1.1, replace "EN ISO 14971" *with* "EN ISO 14971:2012".

In 4.1.1, delete the last (third) paragraph.

In 4.2, add "-braking and acceleration" *to the heading.*

Replace 4.3.1 with the following:

"**4.3.1 General**

Electrical installations added to the one of the base vehicle shall comply with those clauses of IEC 60364-7-721:2007 which are applicable to ambulances.".

Replace 4.3.2 with the following:

"**4.3.2 Electromagnetic compatibility (EMC) – Communication equipment**

Communication equipment (e.g. radio installation) shall comply with national regulations.

For the supply system of the medical equipment the EN 60601-1 and EN 60601-2 series shall apply.

To minimize any risk to the safe operation of the complete ambulance and any of the equipment operated on or in the vehicle from the effects of electromagnetic influences created by the vehicle or its equipment, the complete operational vehicle should consists of components, equipment or sub systems that complies or are certified as conforming to the respective industry EMC regulations.

NOTE An ambulance as supplied and certified may not be fully equipped and therefore some responsibility for added equipment after conversion rests with the customer/user.".

In 4.3.3, note 2 after Table 1, replace "prioritisation" *with* "prioritization".

In 4.3.4.1, third paragraph, delete "220/240 V".

In 4.3.4.3, replace the third paragraph

"The system shall have enough circuits and be so constructed that when/if a circuit fails all illumination and medical technical equipment can be switched to an alternative power source."

with the following:

"The system shall have enough circuits and be so constructed that when/if a circuit fails some illumination and some power supply sources for medical technical equipment still work.".

Add the following new subclause:

"**4.3.5 Visual and audible warning system**

The vehicle shall be fitted with a visual warning and audible warning system to assist emergency passage. These systems shall comply with national regulations where they exist.

NOTE The visual and audible warning system is optional for type A ambulances according to national regulations.".

In 4.4.1, replace the first sentence with the following:

"The interior materials shall conform to the specification of EN 13501-1:2009.".

In 4.4.2, first sentence, delete "vehicles".

In 4.4.3, after Table 3, add the following text:

"If needed, a notice shall be displayed in the drivers' compartment stating the maximum number of seated, wheelchair and stretcher patients and cab occupants that can be carried.

EXAMPLE 1

DRIVER COMPARTMENT: driver and no cab passenger with the following patient's compartment occupants

PATIENT COMPARTMENT:

— 3 seated persons and 1 stretcher person;

— or 4 seated persons and no stretcher;

— or 2 seated persons and 2 wheelchair occupants.

EXAMPLE 2

DRIVER COMPARTMENT: driver and one cab passenger with the following patient's compartment occupants

PATIENT COMPARTMENT:

— 2 seated persons and 1 stretcher person;

— or 2 seated persons and 1 wheelchair.

The notice shall be supplied by the ambulance builder taking account of the maximum weight capacity of the vehicle.".

In 4.4.4, second paragraph, delete the following:

"made of material complying with the requirements of Directive 92/22/EEC modified.".

In 4.4.5.1, in the title to Table 4, replace "patient" *with* "patient's"; *change this throughout the whole document.*

In 4.4.5.1, add the following note at the end of this subclause:

"NOTE The side and/or rear doors can be used as emergency exit.".

In 4.4.5.2, 1st sentence, delete "of" *and add the following after* "door"*:*

"allowing direct access to".

In 4.4.5.2, add the following footnote 7 to b):

"7) The key can be a mechanical or non-mechanical device.".

In 4.4.5.2, last paragraph, replace "door" with the following:

"external door including those not allowing direct access to the patient's compartment,".

In 4.4.5.3, second paragraph, replace "screened" *with* "designed".

In 4.4.5.3, second paragraph, delete the following:

"Windows shall be made of material complying with the requirements of Directive 92/22/EEC modified.".

In 4.4.6, Table 5, delete the column "H_2 minimum" *and* "maximum" add "H_2 minimum" *after* "open" *in the brackets and add* "α" *after* "loading angle" *and* "maximum" *after* "(stretcher)"*to read as follows*:

"Table 5 — Loading area dimensions

	Type of road ambulance			
	A_1	A_2	B	C
Tailgate height (in the open H_2 minimum position) (see Figure 1) [a]	1 800 mm	1 800 mm	1 900 mm	1 900 mm
Loading angle α (stretcher) maximum	16° [b]	16° [b]	16° [b]	16° [b]
Loading height (stretcher)	When the patient is manually loaded or unloaded on the stretcher, the centre of the stretcher handles shall be no more than 825 mm above ground level. The maximum height of either the floor or the loading holding assembly above ground level shall not exceed 750 mm at net vehicle mass plus loose equipment.			

A From ground to lowest point of fully opened tailgate at gross vehicle mass.

B The loading angle shall be kept as low as possible.

".

In 4.4.6, second paragraph (after Table 5), replace "a anti-slip" *with* "an anti-slip" *and delete* "constant".

In 4.4.6, Figure 1, add the following key:

Key

H_2 tailgate height

α loading angle

In 4.5.1, seventh paragraph (beginning with "Drawers"), replace twice "should" *with* "shall".

In 4.5.1, tenth paragraph (beginning with "If the..."), replace "EN 1865" *with* "EN 1865-4:2012".

In 4.5.2.2, add the following note at the end of the subclause and before the figures: