SLOVENSKI STANDARD
SIST EN 1789:2007

01-september-2007

Nadomeġ a:
SIST EN 1789:2000
SIST EN 1789:2000/A1:2003

Medicinska vozila in pripadajoļ a oprema - Reġevalna vozila

Medical vehicles and their equipment - Road ambulances

Rettungsdienstfahrzeuge und deren Ausrüstung - Krankenkraftwagen

Véhicules de transport sanitaire et leurs équipements - Ambulances routieres

Ta slovenski standard je istoveten z: EN 1789:2007

ICS:

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

SIST EN 1789:2007 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 1789

May 2007

ICS 11.160; 43.160

Supersedes EN 1789:1999

English Version

Medical vehicles and their equipment - Road ambulances

Véhicules de transport sanitaire et leurs équipements - Véhicule d'ambulances

Rettungsdienstfahrzeuge und deren Ausrüstung - Krankenkraftwagen

This European Standard was approved by CEN on 24 February 2007.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN member.

This European Standard exists 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 Management Centre has the same status as the official versions.

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

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN 1789:2007: E

Contents

Page

Foreword

This document (EN 1789:2007) has been prepared by Technical Committee CEN/TC 239 “Rescue systems”, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2007, and conflicting national standards shall be withdrawn at the latest by November 2007.

This document supersedes EN 1789:1999.

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.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

1 Scope

This European Standard specifies requirements for the design, testing, performance and equipping of road ambulances used for the transport and care of patients. It contains requirements for the patient's compartment.

This European Standard does not cover the requirements for approval and registration of the vehicle and the training of the staff which is the responsibility of the authority/authorities in the country where the ambulance is to be registered.

This European Standard is applicable to road ambulances capable of transporting at least one person on a stretcher.

Requirements are specified for categories of road ambulances based in increasing order of the level of treatment that can be carried out. These are the patient transport ambulance (types A_1 A_2), the emergency ambulance (type B) and the mobile intensive care unit (type C).

This European Standard gives general requirements for medical devices carried in road ambulances and used therein and outside hospitals and clinics in situations where the ambient conditions can differ from normal indoor conditions.

2 Normative references

The following referenced documents are indispensable for the application 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 3-7, *Portable fire extinguishers — Part 7: Characteristics, performance requirements and test methods*

EN 420, *Protective gloves — General requirements and test methods*

EN 455-1, *Medical gloves for single use — Part 1: Requirements and testing for freedom from holes*

EN 455-2, *Medical gloves for single use — Part 2: Requirements and testing for physical properties*

EN 471:2003, *High-visibility warning clothing for professional use — Test methods and requirements*

EN 737-1:1998, *Medical gas pipeline systems — Part 1: Terminal units for compressed medical gases and vacuum*

EN 737-3:1998, *Medical gas pipeline systems — Part 3: Pipelines for compressed medical gases and vacuum*

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

EN 794-3, *Lung ventilators — Part 3: Particular requirements for emergency and transport ventilators*

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

EN 1041, *Information supplied by the manufacturer with medial devices*

EN 1865, *Specifications for stretchers and other patient handling equipment used in road ambulances*

EN 12470-1, *Clinical thermometers — Part 1: Metallic liquid-in-glass thermometers with maximum device*

EN 13544-1, *Respiratory therapy equipment — Part 1: Nebulizing systems and their components*

EN 14052, *High performance industrial helmets*

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

EN 60068-2-29, *Basic environmental testing procedures — Part 2: Tests; test Eb and guidance: bump (IEC 60068-2-29:1987)*

EN 60068-2-32, *Basic environmental testing procedures — Part 2: Tests; test Ed: free fall (IEC 60068-2-32:1975 + A1:1982 + A2:1990)*

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)*

EN 60601-1 (all parts), *Medical electrical equipment*

EN 60601-2 (all parts), *Medical electrical equipment*

EN 60601-2-4, *Medical electrical equipment — Part 2-4: Particular requirements for the safety of cardiac defibrillators (IEC 60601-2-4:2002)*

EN ISO 407, *Small medical gas cylinders — Pin-index yoke- type valve connections (ISO 407:2004)*

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 10079-1:1999, *Medical suction equipment — Part 1: Electrically powered suction equipment — Safety requirements (ISO 10079-1:1999)*

EN ISO 10079-2:1999, *Medical suction equipment — Part 2: Manually powered suction equipment (ISO 10079-2:1999)*

EN ISO 10079-3:1999, *Medical suction equipment — Part 3: Suction equipment powered from a vacuum or pressure source (ISO 10079-3:1999)*

EN ISO 10524-1, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices (ISO 10524-1:2006)*

EN ISO 10524-3, *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves (ISO 10524-3:2005)*

EN ISO 11197:2004, *Medical supply units (ISO 11197:2004)*

EN ISO 14971, *Medical devices — Application of risk management to medical devices (ISO 14971:2007)*

prEN ISO 15002, *Flow-metering devices for connection to terminal units of medical gas pipeline systems (ISO/DIS 15002:2006)*

EN ISO 19054, *Rail systems for supporting medical equipment (ISO 19054:2005)*

EN ISO 20345, *Personal protective equipment — Safety footwear (ISO 20345:2004)*

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

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)]

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

ISO 5128:1980, *Acoustics— Measurement of noise inside motor vehicles*

3 Terms and definitions

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

3.1
patient and emergency patient

3.1.1
patient
person whose condition requires appropriately trained personnel to provide medical care and/or suitable transport

3.1.2
emergency patient
patient who through sickness, injury or other circumstances is in immediate or imminent danger to life unless emergency treatment and/or monitoring and suitable transport to diagnostic facilities or medical treatment is provided

3.2
ambulance
vehicle or craft intended to be crewed by a minimum of two appropriately trained staff for the provision of care and transport of at least one stretchered patient

3.3
types of road ambulances[2)]

3.3.1
type A: patient transport ambulance
road ambulance designed and equipped for the transport of patients who are not expected to become emergency patients.

Two types of patient transport ambulance exist:

type A_1: suitable for transport of a single patient;

type A_2: suitable for transport of one or more patient(s) (on stretcher(s) and/or chair(s))

3.3.2
type B: emergency ambulance
road ambulance designed and equipped for the transport, basic treatment and monitoring of patients

---

1) IEC/TC 64 “Electrical installations and protection against electric shock” is developing the revision of IEC 60364-7-708. The draft is presently at the DIS stage. The standard, when ready, will be published as the first edition of the new section 7-721 “Electrical installations in caravans and motor caravans”.

2) Road ambulances are road vehicles which comply with type approval for special use vehicles according to Directive 70/156/EEC in the last applicable amended version.

3.3.3
type C: mobile intensive care unit
road ambulance designed and equipped for the transport, advanced treatment and monitoring of patients

3.4
net vehicle mass
unloaded mass
vehicle mass according to 92/21/EEC modified of the road ambulance including the driver taken as 75 kg and all fixed installations

NOTE Loose portable patient handling, sanitary, medical and technical equipment are not included in net vehicle mass.

3.5
permissible gross vehicle mass
permissible total mass
vehicle mass comprising the net vehicle mass, the mass of sanitary, medical and technical equipment, the mass of passengers, taken as 75 kg per person, and any reserve mass

NOTE The permissible gross vehicle mass should be specified by the chassis manufacturer in accordance with Directive 70/156/EEC.

3.6
loading capacity
difference between the gross vehicle mass and the net vehicle mass

NOTE This represents the mass that may be distributed on the road ambulance such that the permissible axle loads are not exceeded.

3.7
fixation system
system or device to ensure the permanent fixation of medical devices or other equipment into the ambulance

3.8
maintain system
bracket or other interface device used to secure a mobile or transportable item of equipment or medical device of the vehicle without the use of tools

4 Requirements

4.1 General requirements

4.1.1 General

The road ambulance shall comply with the requirements of Directive 70/156/EEC, and separate Directives, for ambulances or corresponding national requirements for approval of vehicles.

Road ambulances equipment shall, when operated in normal use and maintained according to the instructions of the manufacturer, cause no safety hazard which could reasonably be foreseen using risk management procedures in accordance with EN ISO 14971 and which is connected with their intended application, in normal condition and in single fault condition.

Annex B and C give an example of "test summery" and "certificate of compliance".

4.1.2 Maximum overall dimensions

The maximum overall dimensions shall be in accordance with the following:

— length in accordance with Directive 92/21/EEC modified;

— height 3 000 mm (measured at net vehicle mass excluding flexible antenna);

— width in accordance with Directive 92/21/EEC modified.

4.1.3 Wheel arch clearance

Vehicle converters shall maintain the minimum wheel arch clearance specified by the chassis manufacturer.

4.2 Performance

4.2.1 Acceleration

A road ambulance loaded to permissible gross vehicle mass shall be able to accelerate from 0 km/h to 80 km/h within 35 s.

4.2.2 Braking

An original equipment manufacturer's anti-lock braking system shall be fitted.

4.2.3 Safety system

The vehicle should be fitted with a control system for stabilisation and a passive safety system.

NOTE Examples of a control system for stabilisation are an electronic brake distribution system and traction control. Examples of a passive safety system could be an air bag, a collapsible steering column and an energy absorbing body structure.'

4.3 Electrical requirements

4.3.1 General

Electrical installations shall comply with those clauses of IEC 60364-7-708 which are applicable to ambulances.

NOTE 1 The reference to IEC 60364-7-708 does not apply to the original electrical equipment, which is already covered by the type approval of the base vehicle.

The vehicle shall be fitted with a visual and audible warning system to assist emergency passage.

NOTE 2 The visual and audible warning system is optional for type A ambulances according to national regulations.

4.3.2 Electromagnetic compatibility (EMC)

4.3.2.1 General

To minimise 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, each item shall comply with the appropriate EMC regulation(s).

The complete operational vehicle shall consist of components, equipment or sub systems that are certified as conforming to the respective industry EMC regulations.

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

4.3.2.2 Communication equipment

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

4.3.2.3 Electric/electronic system and components

The vehicle's electric/electronic system, components, sub systems and all permanently fixed equipments shall be e-marked in accordance with Directive 72/245/EEC modified.

NOTE It is recommended that the electrical medical equipment can withstand the exposure of radiated RF field strength of 20 V/m, measured according to IEC 60601-1-2, be considered as the minimum acceptable limit.

4.3.3 Battery and alternator

Batteries shall be positioned to allow maintenance without removing the battery from its securing device. The construction of the battery and all connections to it shall be such as to prevent any possibility of an inadvertent short circuit.

For types A_2, B and C road ambulances the electrical system shall be capable of holding a reserve of electrical power for restarting the engine.

The characteristics of starter batteries shall comply with Table 1. The characteristics of additional batteries, if fitted, shall comply with Table 1.

NOTE 1 Additional batteries may be required to power the medical devices carried on board and the intended use of the ambulance.

The characteristics of the alternator shall comply with Table 1.

Table 1 — Minimum capacity/power

		Type of road ambulance			
		A_1	A_2	B	C
Starter battery(ies)	Nominal voltage 12 V	54 Ah	54 Ah up to 4 seats and 80 Ah more than 4 seats in the compartment	80 Ah	80 Ah
	Nominal voltage 24 V	–	–	63 Ah (2 × 12 V)	63 Ah (2 × 12 V)
Additional [b] battery(ies)	Nominal voltage 12 V	–	–	80 Ah [a]	80 Ah
	Nominal voltage 24 V	–	–	63 Ah [a] (2 × 12 V)	63 Ah (2 × 12 V)
Alternator power		700 W	700 W	1 200 W	1 200 W

[a] Recommended for special operational conditions.

[b] Additional batteries shall have high cyclic stability (e.g. gel batteries) and of a sealed type.

NOTE 2 When the engine is idling electrical stability should be maintained between electrical load and alternator output. In order to achieve this it may be necessary to fit an electrical load prioritisation device to the vehicle.

4.3.4 Electrical installation

4.3.4.1 In type B and C road ambulances there shall be a recessed externally mounted power connector to enable external power to be provided for operations such as the following:

— charging battery(ies);

— operating medical devices, when installed;

— operating a patient compartment heater, when installed;

— operating an engine preheater, when installed.

The connector for 110 V or 220/240 V, shall be a male connector and not interfere with the electrical and mechanical safety.

It shall be not possible to start the engine whilst it is connected to an external 220/240 V power supply unless an automatic mechanical disconnection is fitted.

If no automatic mechanical disconnection is fitted, the connector shall be on the driver's side.

The 110 V or 220/240 V circuit shall be protected either by an "earth leakage device" with a maximum setting of 30 mA or by a separate transformer. If the protection is given only by an "earth leakage device" there shall be a label near the plug that reads as follows: "CAUTION! CONNECT ONLY TO AN AUTHORISED SOCKET."

4.3.4.2 The patient's compartment shall be fitted with the minimum number of connections as given in Table 2. For these connections a permanent power supply shall exist.

Table 2 — 12 V connections for medical devices in patient's compartment

	Type of road ambulance			
	A_1	A_2	B	C
Minimum number of connections	2	2	4	4

4.3.4.3 Any additional electrical systems fitted to the base vehicle shall be separate from the base vehicle electrical system and the body or chassis shall not be used as an earth return for additional circuits.

All circuits in the additional system(s) shall have separate overload protection[3)]. All circuits shall be well defined and cables clearly marked at the connection points and at a maximum of 1m intervals along its length.

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.

4.3.4.4 The wiring and, where applicable conduits, shall withstand vibrations. No wiring shall be located in or pass through conduit intended for medical gas installation. The wiring shall not be loaded higher than that stated by the wire manufacture.

4.3.4.5 Where there are different voltage systems, the connections shall be non-interchangeable.

---

3) Overload protection may consist of either fuses or so called Electronic Management Control systems.