Nederlandse norm

NEN-EN 1789+A2

(en)

Medische voertuigen en hun uitrusting - Ambulances

Medical vehicles and their equipment - Road ambulances

Vervangt NEN-EN 1789:2007+A1:2010;
NEN-EN 1789:2007+A1:2010/Ontw. A2:2014

ICS 11.160; 43.160
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Normcommissie 301094 "Ambulances en uitrusting"

NEN

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EUROPEAN STANDARD **EN 1789:2007+A2**

NORME EUROPÉENNE

EUROPÄISCHE NORM

September 2014

ICS 11.160; 43.160

Supersedes EN 1789:2007+A1:2010

English Version

Medical vehicles and their equipment - Road ambulances

Véhicules de transport sanitaire et leurs équipements - Ambulances routières

Rettungsdienstfahrzeuge und deren Ausrüstung - Krankenkraftwagen

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Foreword

This document (EN 1789:2007+A2:2014) 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of an identical text or by endorsement, at the latest by March 2015, and conflicting national standards shall be withdrawn at the latest by March 2015.

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This document includes Amendment 1, approved by CEN on 2010-03-06 and Amendment 2, approved by CEN on 2014-07-14.

This document supersedes ⟨A2⟩ EN 1789:2007+A1:2010 ⟨A2⟩.

The start and finish of text introduced or altered by amendment is indicated in the text by tags ⟨A1⟩ ⟨A1⟩ and ⟨A2⟩ ⟨A2⟩.

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, 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 the United Kingdom.

〈A2〉 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 (Read ambulances).

NOTE Such as the demonstration of compliance to the requirements of 4.5.9 or 4.3. 〈A2〉

1) 〈A2〉 The first amendment published in 2010 only updates Table ZA.1 to consider the revision of Directive 93/42/EEC. 〈A2〉

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.

[A2] EN 3-7:2004+A1:2007 [A2], *Portable fire extinguishers — Part 7: Characteristics, performance requirements and test methods*

[A2] EN 420:2003+A1:2009 [A2], *Protective gloves — General requirements and test methods*

[A2] EN 455-1:2000 [A2], *Medical gloves for single use — Part 1: Requirements and testing for freedom from holes*

[A2] EN 455-2:2009+A2:2013 [A2], *Medical gloves for single use — Part 2: Requirements and testing for physical properties*

[A2] *deleted text* [A2]

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*

[A2] *deleted text* [A2]

[A2] EN 794-3:1998+A2:2009 [A2], *Lung ventilators — Part 3: Particular requirements for emergency and transport ventilators*

[A2] *deleted text* [A2]

[A2] EN 1041:2008+A1:2013, *Information supplied by the manufacturer of medical devices* [A2]

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[A2] EN 1865-1:2010, *Patient handling equipment used in road ambulances — Part 1: General stretcher systems and patient handling equipment* [A2]

[A2] 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 — Part 5: Stretcher support* [A2]

[A2] EN 12470-1:2000+A1:2009 [A2], *Clinical thermometers — Part 1: Metallic liquid-in-glass thermometers with maximum device*

[A2] EN 13501-1:2007+A1:2009, *Fire classification of construction products and building elements — Part 1: Classification using test data from reaction to fire tests* [A2]

[A2] EN 13544-1:2007+A1:2009 [A2], *Respiratory therapy equipment — Part 1: Nebulizing systems and their components*

[A2] EN 14052:2012+A1:2012 [A2], *High performance industrial helmets*

[A2] EN 60068-2-6:2008, *Environmental testing — Part 2-6: Tests — Tests Fc: Vibration (sinusoidal) (IEC 60068-2-6:2007)* [A2]

[A2] EN 60068-2-29:1993 [A2], *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)*

[A2] EN 60068-2-64:2008, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance (IEC 60068-2-64:2008)* [A2]

EN 60601-1, *Medical electrical equipment*

EN 60601-2, *Medical electrical equipment*

[A2] 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)* [A2]

[A2] EN ISO 407:2004 [A2], *Small medical gas cylinders - Pin-index yoke-type valve connections (ISO 407:2004)*

[A2] *deleted text* [A2]

[A2] EN ISO 5359:2008, *Low-pressure hose assemblies for use with medical gases (ISO 5359:2008)* [A2]

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)*

[A2] EN ISO 10524-1:2006 [A2], *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices (ISO 10524-1:2006)*

EN ISO 10524-3:2006, *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 14971:2012, *Medical devices — Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)*

EN ISO 15002:2008, *Flow-metering devices for connection to terminal units of medical gas pipeline systems (ISO 15002:2008)*

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 19054:2006, *Rail systems for supporting medical equipment (ISO 19054:2005)*

EN ISO 20345:2011, *Personal protective equipment — Safety footwear (ISO 20345:2011)*

EN ISO 20471:2013, *High visibility clothing — Test methods and requirements (ISO 20471:2013, Corrected version 2013-06-01)*

deleted text

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)*

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)*

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)*

deleted text

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

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
〚A2〛 *deleted text* 〚A2〛
〚A2〛 *deleted text* 〚A2〛 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.

〚A2〛 **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. 〚A2〛

〚A2〛 *deleted text* 〚A2〛

〚A2〛 **3.6** 〚A2〛
fixation system
system or device to ensure the permanent fixation of medical devices or other equipment into the ambulance

〚A2〛 **3.7** 〚A2〛
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

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2) Road ambulances are road vehicles which comply with type approval for special use vehicles according to 〚A2〛 Directive 2007/46/EEC 〚A2〛 in the last applicable amended version.

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