MEDITSIINIS KASUTATAVAD LIIKLUSVAHENDID JA NENDE VARUSTUS. KIIRABIAUTOD

Medical vehicles and their equipment - Road ambulances

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 1789:2020 sisaldab Euroopa standardi EN 1789:2020 ingliskeelset teksti.	This Estonian standard EVS-EN 1789:2020 consists of the English text of the European standard EN 1789:2020.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 02.09.2020.	Date of Availability of the European standard is 02.09.2020.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.160, 43.160

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN 1789

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English Version

Medical vehicles and their equipment - Road ambulances

Véhicules de transport sanitaire et leurs équipements - Ambulances routières

Rettungsdienstfahrzeuge und deren Ausrüstung - Krankenkraftwagen

This European Standard was approved by CEN on 13 April 2020.

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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-CENELEC Management Centre has the same status as the official versions.

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

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European foreword

This document (EN 1789:2020) 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of an identical text or by endorsement, at the latest by February 2021, and conflicting national standards shall be withdrawn at the latest by March 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 1789:2007+A2:2014.

This document has been prepared under a standardization request 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 organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

Road ambulances are subject to a higher risk in use. The exact circumstances of operation cannot always be planned or anticipated in detail.

Vehicles are designed so as to be safe. Design requirements can be derived from European and national occupational safety and health legislation.

Under EU law, employers are responsible for carrying out a risk assessment (89/391/EEC, OSH framework directive) and for provision of safe work equipment (89/655/EEC, use of work equipment directive) that allows employees to work without their health being at risk.

The document was first developed in the late 1990s to define a common approach to requirements to enhance patient and crew safety. The document has evolved and matured through several amendments and revisions.

This latest revision work of EN 1789 has had two key objectives:

— The first objective was to revise the technical side of the document with more manageable verification in mind, while maintaining the high quality and strict nature of the requirements.

— The second objective was to check all the references and regulations, paying special attention to EU regulations and updated standardization rules.

Testing of special purpose vehicle, such as an ambulance, is complex. Multiple functions (e.g. fixations, maintain systems, noise, illumination, heating, cooling etc.) may require numerous tests, which can be destructive. In this edition, carefully planned tests according to worst-case scenario strategies have reduced the number of destructive tests without sacrificing test qualities.

The previous edition of this standard (EN 1789:2007+A2:2014) contained a number of direct references to EU regulations. According to CEN Internal Regulations Part 3:2017 and to avoid duplication as well as outdated references and to enable use of this standard independently of the ECE rules, EU regulations and directives, these references have now been removed from the normative section of the standard.

This document is a reference document which can be used in support of regulations.

For the purpose of verification of an ambulance according to EU vehicle approval process, a section of EN 1789:2007+A1:2010+A2:2014 (i.e. patient's compartment) has been referenced directly in Regulation (EU) 2018/858.

CEN/TC 239 has agreed to a transition period of a maximum of 18 months in order to accommodate the different organisational structures that are necessary for the transport of patients are responsible for providing sufficient time for the technical implementation. At the date of publication of EN 1789, the presumption of conformity of the superseded standard has not yet been established in the Official Journal of the European Union. Users of the standard are invited to check the date in the Official Journal of the European Union against the transition period established by CEN/TC 239.

1 Scope

This document specifies requirements for the design, testing, performance and equipping of road ambulances used for the transport, monitoring, treatment and care of patients. It contains requirements for the patient's compartment in terms of the working environment, ergonomic design and the safety of the crew and patients. This document does not cover the training of the crew, which is the responsibility of the authority/authorities in the country where the ambulance is to be registered.

This document is applicable to road ambulances capable of transporting at least one patient on a stretcher and excludes the transportation of hospital beds.

This document also specifies requirements for ambulances intended to carry transport incubator systems.

This document covers the specific requirements of each type of road ambulance, which are designated according to the patient condition.

This document 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 documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

CEN/TS 16165:2016, *Determination of slip resistance of pedestrian surfaces - Methods of evaluation*

DIN 51130:2014, *Testing of floor coverings - Determination of the anti-slip property - Workrooms and fields of activities with slip danger - Walking method - Ramp test*

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

EN 443:2008, *Helmets for fire fighting in buildings and other structures*

EN 455-1:2020, *Medical gloves for single use - Part 1: Requirements and testing for freedom from holes*

EN 455-2:2015, *Medical gloves for single use - Part 2: Requirements and testing for physical properties*

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

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

EN 1865-1:2010+A1:2015, *Patient handling equipment used in road ambulances - Part 1: General stretcher systems and patient handling equipment*

EN 1865-2:2010+A1:2015, *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*

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

EN 13544-1:2019, *Respiratory therapy equipment - Part 1: Nebulizing systems and their components*

EN 13976-1:2018, *Rescue systems - Transportation of incubators - Part 1: Interface requirements*

EN 60601-1:2006+A1:2013, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 + Cor.:2006 + Cor.:2007 + A1:2012)*

EN 60601-1-12:2015, *Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*

EN 60601-2-4:2011, *Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators*

EN 60601-2-27:2014, *Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment*

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

EN ISO 5359:2014+A1:2017, *Anaesthetic and respiratory equipment - Low-pressure hose assemblies for use with medical gases (ISO 5359:2014 + Amd 1:2017)*

EN ISO 9170-1:—,[1] *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum (ISO/DIS 9170-1:2016)*

EN ISO 7396-1:2016+A1:2019, *Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum (ISO 7396-1:2016 + Amd 1:2017)*

EN ISO 10079-1:2015+A1:2019, *Medical suction equipment - Part 1: Electrically powered suction equipment (ISO 10079-1:2015 + Amd 1:2018)*

EN ISO 10079-2:2014, *Medical suction equipment - Part 2: Manually powered suction equipment (ISO 10079-2:2014)*

EN ISO 10079-3:2014, *Medical suction equipment - Part 3: Suction equipment powered from a vacuum or positive pressure gas source (ISO 10079-3:2014)*

EN ISO 10524-1:2019, *Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices (ISO 10524-1:2018)*

EN ISO 10524-2:2019, *Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators (ISO 10524-2:2018)*

EN ISO 10524-3:2019, *Pressure regulators for use with medical gases - Part 3: Pressure regulators integrated with cylinder valves (VIPRs) (ISO 10524-3:2019)*

EN ISO 11197:2018,[2] *Medical supply units (ISO/DIS 11197:2018)*

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[1] Under preparation. Stage at time of publication: prEN ISO 9170-1:2017

EN ISO 14971:2019, *Medical devices - Application of risk management to medical devices (ISO 14971:2019)*

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

EN ISO 15223-1:2016, *Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)*

EN ISO 19054:2006+A1:2016, *Rail systems for supporting medical equipment (ISO 19054:2005+ Amd1:2016)*

EN ISO 20471:2013+A1:2016, *High visibility clothing — Test methods and requirements (ISO 20471:2013, Corrected version 2013-06-01+Amd 1:2016)*

EN ISO 21420:2020-06, *Protective gloves - General requirements and test methods (ISO 21420:2020)*

EN ISO 80601-2-55:2018, *Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 80601-2-55:2018)*

EN ISO 80601-2-61:2019, *Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO 80601-2-61:2017, Corrected version 2018-02)*

IEC 60364-7-721:2017, *Low-voltage electrical installations — Part 7-721: Requirements for special installations or locations — Electrical installations in caravans and motor caravans*

ISO 3795:1989, *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*

[2] Under preparation. Stage at time of publication: EN ISO 11197:2018