ILNAS

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ILNAS-EN 1789:2020+A1:2023

Medical vehicles and their equipment - Road ambulances

Véhicules de transport sanitaire et leurs équipements - Ambulances routières

Rettungsdienstfahrzeuge und deren Ausrüstung - Krankenkraftwagen

12/2023

National Foreword

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EUROPEAN STANDARD
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Rettungsdienstfahrzeuge und deren Ausrüstung - Krankenkraftwagen

This European Standard was approved by CEN on 13 April 2020 and includes Amendment approved by CEN on 21 September 2023. This European Standard was corrected and reissued by the CEN-CENELEC Management Centre on 31 January 2024.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN 1789:2020+A1:2023) 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of an identical text or by endorsement, at the latest by June 2024, and conflicting national standards shall be withdrawn at the latest by June 2024.

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.

〚A1〛 This document supersedes EN 1789:2020 〈A1〛.

This document includes Amendment 1, approved by CEN on 2023-09-21.

The start and finish of text introduced or altered by amendment is indicated in the text by tags 〚A1〛 〈A1〛

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.

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

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, Türkiye 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.

A1 This revision in 2020 had two key objectives: A1

— 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.

A1 The previous edition EN 1789:2007+A2:2014 A1 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 A1 EN 1789:2020 A1 (i.e. patient's compartment) has been referenced directly in Regulation (EU) 2018/858.

A1 The energy sources for motor vehicles are in turmoil due to environmental fight against global climate warming. Alternative energies are becoming more regular in motor vehicles and electric vehicles are already common by most vehicle manufacturers.

In all standardization criteria, combustion engine characteristics have guided the requirements. Therefore, the most obvious ambulance standard requirements (EN 1789) need adjustments introduced by an Amendment to allow verification of electric engine ambulances as compliant to this document. A1

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.

〚A1〛 EN 16165:2021, *Determination of slip resistance of pedestrian surfaces - Methods of evaluation* 〚A1〛

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*

〚A1〛 EN 455-1:2020+A1:2022, *Medical gloves for single use - Part 1: Requirements and testing for freedom from holes* 〚A1〛

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*

〚A1〛 EN ISO 20417:2021, *Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)* 〚A1〛

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

〚A1〛 prEN 1865-2:2022[1], *Patient handling equipment used in ambulances - Part 2: Power assisted stretcher* 〚A1〛

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

EN 1865-5:2012, *Patient handling equipment used in ambulances - Part 5: Stretcher support*

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

〉A1〈 EN ISO 27427:2019, *Anaesthetic and respiratory equipment - Nebulizing systems and components (ISO 27427:2013)* 〉A1〈

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)*

〉A1〈 EN 60601-1-12:2015+A1:2020, *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 (IEC 60601 1 12:2014 + A1:2020)* 〉A1〈

〉A1〈 EN 60601-2-4:2011+A1:2019, *Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators (IEC 60601 2 4:2010 + A1:2018)* 〉A1〈

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

〉A1〈 EN ISO 407:2021, *Small medical gas cylinders - Pin-index yoke-type valve connections (ISO 407:2021)* 〉A1〈

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)*

〉A1〈 EN ISO 9170-1:2020, *Terminal units for medical gas pipeline systems - Part 1: Terminal units for use with compressed medical gases and vacuum (ISO 9170-1:2017)* 〉A1〈

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)*

〉A1〈 EN ISO 10079-1:2022, *Medical suction equipment - Part 1: Electrically powered suction equipment (ISO 10079-1:2022)* 〉A1〈

〉A1〈 EN ISO 10079-2:2022, *Medical suction equipment - Part 2: Manually powered suction equipment (ISO 10079-2:2022)* 〉A1〈

〉A1〈 EN ISO 10079-3:2022, *Medical suction equipment - Part 3: Suction equipment powered from a vacuum or positive pressure gas source (ISO 10079-3:2022)* 〉A1〈

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)*

〉A1〈 EN ISO 11197:2019, *Medical supply units (ISO 11197:2019)* 〉A1〈