



NSAI
Standards

Irish Standard
I.S. EN 1789:2007+A2:2014

Medical vehicles and their equipment - Road ambulances

I.S. EN 1789:2007+A2:2014

Incorporating amendments/corrigenda/National Annexes issued since publication:

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation — recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):

NOTE: The date of any NSAI previous adoption may not match the date of its original CEN/CENELEC document.

This document is based on:

EN 1789:2007+A2:2014

Published:

2014-09-10

This document was published under the authority of the NSAI and comes into effect on:

2014-09-27

ICS number:

11.160

43.160

NOTE: If blank see CEN/CENELEC cover page

NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie
W NSAI.ie

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

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

This European Standard was approved by CEN on 24 February 2007 and includes Amendment 1 approved by CEN on 6 March 2010 and Amendment 2 approved by CEN on 14 July 2014.

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

CEN members are the national standards bodies of 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 United Kingdom.



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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

EN 1789:2007+A2:2014 (E)




Contents

Page

Foreword.....	5
[A₂] Introduction [A₂]	6
1 Scope	7
2 Normative references	7
3 Terms and definitions	9
4 Requirements	11
4.1 General requirements.....	11
4.1.1 General.....	11
4.1.2 Maximum overall dimensions.....	11
4.1.3 Wheel arch clearance	11
4.2 [A₂] Performance-braking and acceleration [A₂]	11
4.2.1 Acceleration	11
4.2.2 Braking.....	12
4.2.3 Safety system.....	12
4.3 Electrical requirements	12
4.3.1 General.....	12
4.3.2 Electromagnetic compatibility (EMC) – Communication equipment	12
4.3.3 Battery and alternator	12
4.3.4 Electrical installation	13
4.3.5 Visual and audible warning system	14
4.4 Vehicle body.....	14
4.4.1 Fire safety	14
4.4.2 Driver's seat configuration	14
4.4.3 Minimum loading capacity	14
4.4.4 Bulkhead.....	15
4.4.5 Openings (doors, windows, emergency exits)	16
4.4.6 Loading area.....	17
4.5 Patient's compartment	18
4.5.1 General.....	18
4.5.2 Patient's compartment dimensions	19
4.5.3 Patient and attendant seating.....	23
4.5.4 Ventilation and anaesthetic gas scavenging systems.....	24
4.5.5 Temperature system.....	25
4.5.6 Interior lighting.....	25
4.5.7 Interior noise level	26
4.5.8 Holding system for infusion	26
4.5.9 Mounting systems	26
4.5.10 Mass reserve	27
5 Testing	27
5.1 General.....	27
5.2 Testing of the interior noise level	27
5.2.1 [A₂] Specific measurement conditions [A₂]	27
5.2.2 Measurements.....	28
5.2.3 Establishment of compliance	29
5.3 Testing of the acceleration	30
5.4 Testing of maintain systems and fixations of the equipment in the patient's compartment	30
5.4.1 General.....	30

5.4.2	Testing of the stretcher fixations on the vehicle floor	32
5.4.3	Testing of the medical devices fixations	33
5.4.4	Testing of furniture.....	33
5.4.5	Test procedure.....	33
5.5	A₂ Testing of rounded edges and radius inside the patient's compartment A₂	34
5.5.1	A₂ Testing of rounded edges A₂	34
5.5.2	Testing of rounded edges and radius inside the patient's compartment.....	35
5.6	Procedure to verify the patient's compartment specifications	35
5.7	Procedure to verify the loading area specifications	36
5.7.1	General	36
5.7.2	Procedure to verify the loading angle of 16°	36
5.8	Procedure to verify the dimensions of the patient's compartment.....	37
5.8.1	Type A and B road ambulances	37
5.8.2	Type C road ambulances	37
5.9	Procedure to verify the seats dimensions of the patient's compartment	38
5.10	Testing of the ventilation system	39
5.11	Testing of the heating system.....	39
5.12	Testing of the cooling system.....	40
5.12.1	Test procedure.....	40
5.12.2	Testing of independent air conditioning system	40
5.13	Testing of interior lighting	41
5.14	Testing of infusion holding system	41
6	Medical devices	41
6.1	Provision of medical devices	41
6.2	Medical devices storage	41
6.3	Requirements for medical devices	42
6.3.1	General	42
6.3.2	Temperature	42
6.3.3	Humidity and ingress of liquids	42
6.3.4	Mechanical strength	42
6.3.5	Fixation of devices	43
6.3.6	Electrical safety	43
6.3.7	User interface.....	43
6.3.8	Gas installation.....	43
6.3.9	Marking and instructions.....	45
6.3.10	Maintenance.....	45
6.4	Mechanical strength – Test methods for medical devices for use in road ambulances	45
6.4.1	Vibration and bump test	45
6.4.2	Free fall.....	46
6.5	List of equipment.....	46
7	Conformity assessment.....	53
8	Requirements to be met for a Certificate of Compliance	53
Annex A	(informative) A₂ Test summary A₂	55
Annex B	(informative) A₂ Definition of ambulance body styles A₂	56
B.1	General	56
B.2	Van based Ambulance	56
B.3	Fully independent box body.....	57
Annex C	(informative) A₂ Recognition A₂	58
C.1	Recognition and visibility of ambulances.....	58
C.2	Recognition of personnel	58

EN 1789:2007+A2:2014 (E)

Annex ZA (informative)   Relationship between this European Standard and the Essential Requirements of EC Directive 93/42/EEC on Medical Devices and Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles  59

Bibliography 60

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.

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

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 $\boxed{A_2}$ EN 1789:2007+A1:2010 $\boxed{A_2}$.

The start and finish of text introduced or altered by amendment is indicated in the text by tags $\boxed{A_1}$ $\boxed{A_1}$ and $\boxed{A_2}$ $\boxed{A_2}$.

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.

EN 1789:2007+A2:2014 (E)**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 amendment¹⁾ 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. 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 A₁ A₂), 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 3-7:2004+A1:2007, *Portable fire extinguishers — Part 7: Characteristics, performance requirements and test methods*

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

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

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

deleted text

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*

deleted text

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

deleted text

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

This is a free preview. Purchase the entire publication at the link below:

[Product Page](#)

-
- [Looking for additional Standards? Visit Intertek Inform Infostore](#)
 - [Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation](#)
-