

**Meditisiinis kasutatavad liiklusvahendid ja nende varustus. Kiirabilennukid/helikopterid. Osa 2: Kiirabilennukite/helikopterite tootmis- ja tehnilised nõuded**

Medical vehicles and their equipment - Air ambulances  
- Part 2: Operational and technical requirements of air ambulances

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN 13718-2:2008 sisaldab Euroopa standardi EN 13718-2:2008 ingliskeelset teksti.</p> <p>Standard on kinnitatud Eesti Standardikeskuse 25.09.2008 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 13.08.2008.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN 13718-2:2008 consists of the English text of the European standard EN 13718-2:2008.</p> <p>This standard is ratified with the order of Estonian Centre for Standardisation dated 25.09.2008 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.</p> <p>Date of Availability of the European standard text 13.08.2008.</p> <p>The standard is available from Estonian standardisation organisation.</p>
--	---

ICS 11.040.01, 11.160, 49.020

**Võtmesõnad:**

### Standardite reprodutseerimis- ja levitamiseõigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonilisse süsteemi või edastamine ükskõik millises vormis või millisel teel on keelatud ilma Eesti Standardikeskuse poolt antud kirjaliku loata.

Kui Teil on küsimusi standardite autorikaitse kohta, palun võtke ühendust Eesti Standardikeskusega:  
Aru 10 Tallinn 10317 Eesti; [www.evs.ee](http://www.evs.ee); Telefon: 605 5050; E-post: [info@evs.ee](mailto:info@evs.ee)

EUROPEAN STANDARD

**EN 13718-2**

NORME EUROPÉENNE

EUROPÄISCHE NORM

August 2008

ICS 11.040.01; 11.160; 49.020

Supersedes EN 13718-2:2002

English Version

## Medical vehicles and their equipment - Air ambulances - Part 2: Operational and technical requirements of air ambulances

Véhicules sanitaire et leur équipement - Ambulances  
aérienne - Partie 2: Exigences techniques et  
opérationnelles pour les ambulances aériennes

Medizinische Fahrzeuge und ihre Ausrüstung -  
Luftfahrzeuge zum Patiententransport - Teil 2:  
Operationelle und technische Anforderungen an  
Luftfahrzeuge zum Patiententransport

This European Standard was approved by CEN on 11 July 2008.

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

# Contents

Page

Foreword.....	4
Introduction .....	5
1 Scope .....	6
2 Normative references .....	6
3 Terms and definitions .....	7
4 General requirements for air ambulances .....	8
4.1 General.....	8
4.2 Environmental conditions in the patient compartment .....	8
4.2.1 Temperature and humidity.....	8
4.2.2 Variable atmospheric pressure .....	8
4.2.3 Interior light .....	8
4.2.4 Ventilation.....	9
4.2.5 Noise exposure .....	9
4.3 Requirements for electrical power source for medical devices in the patient compartment.....	9
4.4 Electromagnetic interference .....	10
4.5 Rail systems .....	10
4.6 Mechanical vibration .....	10
4.7 Requirements for fixation of medical devices .....	10
4.8 Restraint systems in the patient compartment .....	10
4.9 Patient compartment .....	11
4.9.1 General.....	11
4.9.2 Patient loading and unloading .....	11
4.9.3 Communication systems .....	11
4.9.4 Fire safety requirements .....	12
4.9.5 Emergency exit .....	12
4.10 Lists of equipment.....	12
5 Air ambulances, operation and performance requirements .....	12
5.1 Personnel.....	12
5.1.1 Flight crew .....	12
5.1.2 Medical crew.....	12
5.2 Specific requirements for helicopters operated in Helicopter Emergency Medical Service (HEMS) .....	12
5.2.1 General.....	12
5.2.2 Patient compartment .....	13
5.3 Specific requirements for HICAMS .....	13
5.3.1 General.....	13
5.3.2 Patient compartment .....	13
5.4 Specific requirements for fixed wing air ambulances .....	15
5.4.1 General.....	15
5.4.2 Patient compartment .....	15
6 Gas installations in air ambulances.....	16
6.1 System components.....	16
6.2 General requirements.....	16
6.2.1 Capacity and pressure operating range.....	16
6.2.2 Continuity of supply .....	16
6.3 Supply systems with gas cylinders .....	16
6.4 Supply systems for compressed medical air .....	17
6.5 Supply systems with air compressor .....	17
6.6 Pipeline distribution system.....	18
6.7 Marking and colour coding.....	18

<b>6.8</b>	<b>Alarms</b> .....	<b>19</b>
<b>6.9</b>	<b>Testing</b> .....	<b>19</b>
<b>6.9.1</b>	<b>General</b> .....	<b>19</b>
<b>6.9.2</b>	<b>Test for mechanical integrity for compressed medical gas systems</b> .....	<b>19</b>
<b>6.9.3</b>	<b>Test for leakage on all pipeline systems and for mechanical integrity of vacuum pipeline systems</b> .....	<b>19</b>
<b>6.9.4</b>	<b>Leakage from the compressed medical gas pipelines</b> .....	<b>19</b>
<b>6.9.5</b>	<b>Test for cross connection</b> .....	<b>19</b>
<b>6.10</b>	<b>Maintenance</b> .....	<b>20</b>
<b>Annex A</b>	<b>(normative) Medical devices in air ambulances</b> .....	<b>21</b>
<b>A.1</b>	<b>Patient transfer devices</b> .....	<b>21</b>
<b>A.2</b>	<b>Isolated extremity and upper spinal immobilisation devices</b> .....	<b>21</b>
<b>A.3</b>	<b>Ventilation and respiration devices</b> .....	<b>22</b>
<b>A.4</b>	<b>Medical devices for diagnosis and monitoring</b> .....	<b>23</b>
<b>A.5</b>	<b>Devices for injection and infusion</b> .....	<b>23</b>
<b>A.6</b>	<b>Devices managing of life-threatening problems</b> .....	<b>24</b>
<b>A.7</b>	<b>Bandaging and nursing devices</b> .....	<b>24</b>
<b>A.8</b>	<b>Additional equipment</b> .....	<b>24</b>
<b>Annex B</b>	<b>(normative) Medicinal products and equipment additional to medical devices in air ambulances</b> .....	<b>25</b>
<b>B.1</b>	<b>Medicinal products (drugs)</b> .....	<b>25</b>
<b>B.2</b>	<b>Rescue and protection equipment etc.</b> .....	<b>26</b>
<b>B.3</b>	<b>Communication equipment for medical personnel</b> .....	<b>27</b>
	<b>Bibliography</b> .....	<b>28</b>

## Foreword

This document (EN 13718-2:2008) 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 2009, and conflicting national standards shall be withdrawn at the latest by February 2009.

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 supersedes EN 13718-2:2002.

EN 13718 *Medical vehicles and their equipment — Air ambulances* consists of the following parts:

- *Part 1: Requirements of medical devices used in air ambulances;*
- *Part 2: Operational and technical requirements of air ambulances.*

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 the United Kingdom.

## Introduction

This European Standard provides requirements for air ambulances, and in particular covers requirements for the ambulance role of the aircraft.

Air ambulances are equipped with medical devices as well as drugs and rescue equipment to be used by medical personnel. Requirements for medical devices intended for use in ambulances are provided in EN 13718-1 *Medical vehicles and their equipment — Air ambulances — Part 1: Requirements for medical devices used in air ambulances*. This standard is supplementary to several European Standards as well as laws and regulations providing the requirements for aircraft in order to provide continuous patient care and monitoring during transport in and between various ambulance types and hospitals. The requirements sets covers ambulance flights in general. Several national and regional rules and regulations apply to aircrafts being used as ambulances. This European Standard gives information on these in the annexes and in notes throughout the text. Provisions for the safety and care both of the patient as well as of the crew and the medical personnel are contained in existing national and international laws, regulations and guidelines.

This European Standard provides some general requirements for the safe operation of aircrafts being used as ambulances. These requirements are not covered by the scope of the Medical Device Directive or by international agreements for craft, transportation and traffic. They are provided in order to secure the safe handling of patients. In order to accommodate continuity of patient care between different kinds of ambulances, some specific requirements are given. Requirements are set in order to secure safe use and handling of medical devices.

Aircraft being used as ambulances are equipped with medical devices, medicinal products and rescue equipment to enable the medical personnel to provide continuous patient care. The minima for the medical devices are specified in Annex A. The requirements set out in this European Standard give the minimum provisions for an ambulance service to provide satisfactory care and medical attention to emergency patients as well as other patients during transportation. The requirements are based on the state of the art of today and common practice in Europe.

## 1 Scope

This European Standard specifies the requirements for design, performance and equipping of air ambulances used for the transport and treatment of sick or injured persons. This European Standard is applicable to air ambulances capable of transporting at least one person on a stretcher.

NOTE Requirements are specified for categories of air ambulances based on the different intended use. These are the helicopter emergency medical service (HEMS) the helicopter intensive care medical service (HICAMS) and the fixed wing air ambulance (FWAA).

## 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 143:2000, *Respiratory protective devices — Particle filters — Requirements, testing, marking*

EN ISO 5359, *Low-pressure hose assemblies for use with medical gases*

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

EN 13718-1, *Medical vehicles and their equipment — Air ambulances — Part 1: Requirements for medical devices used in air ambulance*

EN 13976-1, *Rescue systems — Transportation of incubators — Part 1: Interface conditions*

EN 13976-2, *Rescue systems — Transportation on incubators — Part 2: System requirements*

EN ISO 7396-1:2007, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum (ISO 7396-1:2007)*

EN ISO 10524 (all parts), *Pressure regulators for use with medical gases (ISO 10524)*

EN ISO 18777, *Transportable liquid oxygen systems for medical use — Particular requirements (ISO 18777:2005)*

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

ISO 3795:1989, *Road vehicles, and tractors and machinery for agriculture and forestry — Determination of burning behaviour of interior materials*

European Aviation Safety Agency, *EASA Part 21 Certification of aircraft and related products, parts and appliances, and of design and production organisations* <sup>1)</sup>

European Aviation Safety Agency, *EASA CS-23 Certification Specification for Normal, Utility, Aerobatic and Commuter Category Aeroplanes* <sup>1)</sup>

European Aviation Safety Agency, *EASA CS-25 Certification Specification for Large Aeroplanes* <sup>1)</sup>

European Aviation Safety Agency, *EASA CS-27 Certification Specification for Small Rotorcraft* <sup>1)</sup>

European Aviation Safety Agency, *EASA CS-29 Certification Specifications for Large Rotorcraft* <sup>1)</sup>

---

1) <http://www.easa.eu.int/home/index.html>



Joint Aviation Authorities, *JAR-OPS (Joint Aviation Regulations-Operational Specifications) 3 Commercial Air Transportation (Helicopters) (publication available at Information Handling Services, Global Engineering Documents, 15 Inverness Way East, Englewood, Colorado 80112-5776, USA)* <sup>2)</sup>

### 3 Terms and definitions

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

#### 3.1

##### **air ambulance**

aircraft designed to be normally staffed by two medically trained personnel equipped and intended for the transportation of at least one stretcher patient who will receive medical treatment during transport

#### 3.2

##### **medical device**

instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease and injury

#### 3.3

##### **helicopter emergency medical service flight**

##### **HEMS flight**

flight by a helicopter operating under a HEMS approval, the purpose of which is to facilitate emergency medical assistance, where immediate and rapid transportation is essential, by carrying:

- medical personnel and/or
- medical supplies (equipment, blood, organs, drugs) and/or
- ill or injured persons and other persons directly involved

#### 3.4

##### **helicopter intensive care medical service flight**

##### **HICAMS flight**

flight by a helicopter operating under a HEMS approval, especially staffed and equipped for the transportation, medical treatment and care of patients requiring intensive care treatment, mainly in inter-hospital transfers

#### 3.5

##### **fixed wing air ambulance**

##### **FWAA**

aircraft especially equipped for transportation, medical treatment and care of patients, including patients requiring intensive care treatment

#### 3.6

##### **interface**

means or place of interaction between one or more of the medical devices, the ambient conditions, the user, the patient, and when relevant, the various kinds of ambulances

#### 3.7

##### **interoperability**

facility to connect various medical devices that are fixed to patients, into connections of associated medical devices including the possibility of connecting powered medical devices to various kinds of ambulances

---

2) <http://www.jaa.nl/publications/publications.html>