# SLOVENSKI STANDARD
# SIST EN 13718-1:2015

**01-januar-2015**

**Nadomešča:**
**SIST EN 13718-1:2008**

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**Ambulantna vozila in njihova oprema - Ambulantna zračna vozila - 1. del: Zahteve za medicinsko opremo, ki se uporablja v ambulantnih zračnih vozilih**

Medical vehicles and their equipment - Air ambulances - Part 1: Requirements for medical devices used in air ambulances

Medizinische Fahrzeuge und ihre Ausrüstung - Luftfahrzeuge zum Patiententransport - Teil 1: Anforderungen an medizinische Geräte, die in Luftfahrzeugen zum Patiententransport verwendet werden



Véhicules sanitaires et leur équipement - Ambulances aériennes - Partie 1: Exigences pour les dispositifs médicaux utilisés dans les ambulances aériennes

**Ta slovenski standard je istoveten z:** **EN 13718-1:2014**

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**ICS:**

| | | |
|---|---|---|
| 11.160 | Prva pomoč | First aid |
| 49.020 | Letala in vesoljska vozila na splošno | Aircraft and space vehicles in general |

**SIST EN 13718-1:2015** **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN 13718-1

September 2014

ICS 11.040.01; 11.160; 49.020

Supersedes EN 13718-1:2008

English Version

# Medical vehicles and their equipment - Air ambulances - Part 1: Requirements for medical devices used in air ambulances

Véhicules sanitaire et leur équipement - Ambulances aérienne - Partie 1 : Exigences pour les dispositifs médicaux utilisés dans les ambulances aérienne

Medizinische Fahrzeuge und ihre Ausrüstung - Luftfahrzeuge zum Patiententransport - Teil 1: Anforderungen an medizinische Geräte, die in Luftfahrzeugen zum Patiententransport verwendet werden

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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

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

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# Foreword

This document (EN 13718-1:2014) 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 supersedes EN 13718-1:2008.

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, see informative Annex ZA, which is an integral part of this document.

EN 13718-1:2008 has been technically revised. The following points represent the most important changes in the revision:

a) normative references were updated;



b) the following terms and definitions were deleted: 3.3 "HEMS flight", 3.4 "air ambulance flight", 3.5 "non-dedicated aircraft for patient transportation", 3.6 "HICAMS flight", 3.7 "fixed wing air ambulance", 3.10 "interchangeability", 3.11 "flight crew", 3.12 "medical crew";



c) a new Subclause 4.5.4 "Medical devices with 230 V AC power input" was introduced;

d) Subclause 4.4.5 "Inverters" was deleted;

e) Subclause 4.5.4 "Pneumatic power supply" (now Subclause 4.6.4) was revised;

f) Subclause 4.8 "Fire resistance" (now Subclause 4.9) was revised;

g) unclear issues were clarified in this part of the standard and between the two parts of the standard (requirements for patient's compartment illumination, respectively);

h) the standard was modified/integrated to meet the Medical Devices Directive 93/42/EEC requirements.

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

— *Part 1: Requirements for medical devices used in air ambulances*;

— *Part 2: Operational and technical requirements for 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, 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.

## Introduction

This part of EN 13718 gives minimum requirements for interfaces and compatibility of medical devices used in air ambulances. The standards work was called for by the EU Commission by a mandate from the Medical Devices Directive (see Bibliography and Annex ZA).

This part of EN 13718 is supplementary to several other European Standards and gives requirements for medical devices when used in situations where the ambient conditions differ from the normal indoor conditions prevailing within the health care system. Several specific requirements are related to the conditions prevailing in air ambulances. The requirements that are set are carefully selected to ensure interoperability and continuous patient care.

The medical devices are being used by the services in air ambulances. Air ambulances carry medical devices as well as medicinal products and rescue equipment to be used by medical personnel.

The medical devices need to conform to the applicable essential requirements in the Medical Devices Directive. The essential requirements are listed in Annex I of the Medical Devices Directive (MDD). Annex ZA lists the essential requirements that are addressed by the identified clauses of this European Standard.

The environmental conditions for medical devices used in air ambulances are different from those expected in a normal hospital environment. In particular, this implies environmental conditions such as temperature and humidity, vibration and shock caused by movement of the air ambulances, variable atmospheric pressures and electromagnetic disturbances between the air ambulances and the medical device.

## 1 Scope

This European Standard specifies general requirements for medical devices carried in air ambulances and used therein and outside hospitals and clinics in situations where the ambient conditions can differ from normal indoor conditions.

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.

## 2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

EN 13718-2:2008, [1)] *Medical vehicles and their equipment — Air ambulances — Part 2: Operational and technical requirements of air ambulances*

EN 60068-2-31:2008, *Environmental testing — Part 2-31: Tests — Test Ec: Rough handling shocks, primarily for equipment-type specimens (IEC 60068-2-31:2008)*



EN 60529:1991, *Degrees of protection provided by enclosures (IP Code) (IEC 60529:1989)*

EN 60601 (all parts), *Medical electrical equipment (IEC 60601, all parts)*



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

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

EN ISO 10297:2006, *Transportable gas cylinders — Cylinder valves — Specification and type testing (ISO 10297:2006)*

EN ISO 10524-1:2006, *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 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)*

ISO 7000:2012, *Graphical symbols for use on equipment — Registered symbols*

1) EN 13718-2:2008 is bound to be superseded with a new edition.

RTCA DO-160G:2010,[2] *Environmental Conditions and Test Procedures for Airborne Equipment*

## 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 medical personnel equipped and intended for the transportation of at least one stretcher patient who will receive medical treatment during transport

**3.2**
**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

**3.3**
**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

**3.4**
**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



**3.5**
**portable**
term referring to transportable equipment that, once installed and placed into service, is intended to be moved from one location to another while being carried by one or more persons



Note 1 to entry: Equipment can refer to accessories or equipment parts.

Note 2 to entry: See the taxonomy in the rationale for Definition 3.63 in EN 60601-1:2006/A1:2013.

[SOURCE: EN 60601-1:2006/A1:2013, 3.85, modified — The wording of Note 2 to entry has been slightly modified.]

## 4 Requirements for medical devices for air ambulances

### 4.1 General

The manufacturers of all medical devices intended to be used in air ambulances shall ensure that the requirements of this standard are met.

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RTCA, Inc.
1150 18th Street NW
Suite 910
Washington, DC 20036
(202) 833-9339

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## 4.2 Patient and personnel safety

Risks associated with medical devices shall be minimized, using risk management process in accordance with EN ISO 14971:2012, taking account of the intended application of the devices and of known and foreseeable hazards in both normal and fault conditions. When risk analyses are performed, they shall reflect storage, installation, operation in normal use and maintenance according to the instructions of the manufacturer and the ambient conditions of an air ambulance.

## 4.3 User interface

The user interface of the medical device shall be easy to use in an air ambulance.

NOTE 1 See EN 62366:2008 and EN 60601–1–6:2010 for detailed information on how to design an easy to use medical device.

A medical device designated as portable shall be:

— able to be carried inside and outside the aircraft;

— able to be carried by one person.

NOTE 2 See Directive 90/269/EEC for information.

The manufacturer of the medical device shall carry out a risk assessment of the manual handling of the medical device inside and outside of an air ambulance.



NOTE 3 There are several accepted risk assessments methods to use e.g. Key Item Method (KIM), Manual Handling Assessment Charts and EN 1005–2:2003+A1:2008.



Buttons, switches, indicators, controls etc. shall be accessible and readable under the intended operational conditions.

NOTE 4 Intended operational conditions are described as requirements in EN 13718-2:2008.

Medical devices with alarms and signals shall provide a clear visual signal under the intended operational conditions.

When markings and instructions for the use of medical devices are present they shall conform to EN 1041:2008+A1:2013 and EN ISO 15223-1:2012. Graphical symbols shall be derived from harmonized standards when available. Any other symbols used shall be clear in their intentions, and there shall be a description of the meaning on the label or associated literature.

Markings shall remain legible following the test in 5.3.

## 4.4 Environmental conditions and performance of medical devices intended for use in air ambulances

### 4.4.1 Functional temperature range

The medical devices shall function throughout the temperature range from 0 °C to +40 °C and shall function for at least 20 min when placed in an environment at −5 °C after storage at room temperature (20 ± 2) °C.

Following storage under extreme temperature conditions ranging from −20 °C to +50 °C, a medical device shall function within 10 min as intended and for at least 20 min when the medical device is returned to room temperature (20 ± 2) °C.