Meditsiinis kasutatavad liiklusvahendid ja nende varustus. Kiirabilennukid/helikopterid. Osa 1: Nõuded kiirabilennukites/helikopterites kasutatavatele meditsiiniseadmetele

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 13718-1:2008 sisaldab Euroopa standardi EN 13718-1:2008 ingliskeelset teksti.	This Estonian standard EVS-EN 13718-1:2008 consists of the English text of the European standard EN 13718-1:2008.
Standard on kinnitatud Eesti Standardikeskuse 25.09.2008 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	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.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 13.08.2008.	Date of Availability of the European standard text 13.08.2008.
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Võtmesõnad: hospitals, human factors engineering, land vehicles, medicine, patient transport equipment, patients, rescue and ambulance services, rough-terrain vehicles, safety, safety requirements, ships, specification (approval), specifications, testing, transport, vessels

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

Véhicules sanitaire et leur équipment - 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

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

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Foreword

This document (EN 13718-1:2008) 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of an identical text or by endorsement, at the latest by February 2009, and conflicting national standards shall be withdrawn at the latest by February 2009.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 13718-1:2002.

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.

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

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

— *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 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 Device Directive (see Bibliography and Annex ZA).

This European Standard 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 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.

Medical devices need to conform to the applicable essential requirements. The essential requirements are listed in Annex I to the Medical Device Directive (MDD). Annex ZA indicates related essential requirements that are addressed in 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 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 737-1, *Medical gas pipeline systems — Part 1: Terminal units for compressed medical gases and vacuum*

EN 980, *Symbols for use in the labelling of medical devices*

EN 1041, *Information supplied by the manufacturer with medical devices*

EN 13220, *Flow-metering devices for connection to terminal units of medical gas pipeline systems*

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

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

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

EN 60068-2-32:1993, *Basic environmental testing procedures — Part 2: Tests — Test Ed: Free fall (IEC 60068-2-32:1975 + A1:1982 + A2:1990)*

EN ISO 407, *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, *Transportable gas cylinders — Cylinder valves — Specification and type testing (ISO 10297:2006)*

EN ISO 10524-1, *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, *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves (ISO 10524-3:2005)*

EN ISO 14971, *Medical devices — Application of risk management to medical devices (ISO 14971:2007)*

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

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

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

ISO 7137, *Aircraft — Environmental conditions and test procedures for airborne equipment*

European Aviation Safety Agency, *EASA Part 21: Certification of aircraft and related products, parts and appliances, and of design and production organisations* [1)]

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
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
air ambulance flight
usually planned flight with an aircraft which is equipped with medical devices and installations, which are to facilitate medical assistance, where immediate and rapid transportation is not essential by carrying:

— medical personnel and/or

— medical supplies (equipment, blood, organs, drugs) and/or

— ill or injured persons and other persons directly involved

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