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STN	**Prepravné prostriedky záchrannej zdravotnej služby a ich vybavenie Letecké ambulancie Časť 2: Prevádzkové a technické požiadavky na letecké ambulancie**	**STN EN 13718-2+A1** 84 7088

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English Version

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

Véhicules sanitaires et leur équipement - Ambulances aériennes - Partie 2 : Exigences opérationnelles et techniques 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 26 December 2014 and includes Amendment 1 approved by CEN on 16 December 2019.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN 13718-2:2015+A1:2020) 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of an identical text or by endorsement, at the latest by September 2020, and conflicting national standards shall be withdrawn at the latest by September 2020.

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.

This document includes Amendment 1 approved by CEN on 2019-12-16.

This document supersedes A1 EN 13718-2:2015. A1

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 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 13718-2:2008 has been technically revised. The following points represent the most important changes in the revision:

a) clarified unclear issues in this part of the standard and between the two parts of the standard (for example requirements for patient's compartment illumination);

b) changed text related to enhancing safety related to the risk from rotors on helicopters;

c) clarified the requirements for the patient compartment;

d) the standard has been 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 ambulance:*

— *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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

This part of EN 13718 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 air ambulances are provided in EN 13718-1. 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 cover ambulance flights in general. Several national and regional rules and regulations apply to aircraft being used as ambulances. This part of EN 13718 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 part of EN 13718 provides some general requirements for the safe operation of aircraft being used as ambulances. These requirements are not covered by the scope of the Medical Devices Directive or by international agreements for craft, transportation and traffic. They are provided in order to secure the safe and secure 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 part of EN 13718 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.

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 linked with the Medical Devices Directive (see Annex ZA and Bibliography [1]).

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.

Medical devices need to conform to the applicable essential requirements in the Medical Devices Directive, 93/42/EEC. The essential requirements are listed in Annex I of the Medical Devices Directive. Annex ZA in this European Standard lists the essential requirements that are covered 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 part of EN 13718 specifies the requirements for performance and equipping for air ambulances, including requirements for interfaces to medical devices used for the transport and treatment of sick or injured persons. This part of EN 13718 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 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.

EN 3-7:2004+A1:2007, *Portable fire extinguishers — Part 7: Characteristics, performance requirements and test methods*

EN 3-8:2006, *Portable fire extinguishers — Part 8: Additional requirements to EN 3-7 for the construction, resistance to pressure and mechanical tests for extinguishers with a maximum allowable pressure equal to or lower than 30 bar*

[A1] EN 3-9:2006+AC:2007, *Portable fire extinguishers — Part 9: Additional requirements to EN 3-7 for pressure resistance of CO2 extinguishers* [A1]

EN 3-10:2009, *Portable fire extinguishers — Part 10: Provisions for evaluating the conformity of a portable fire extinguisher to EN 3-7*

[A1] EN 143:2000+A1:2017, *Respiratory protective devices — Particle filters — Requirements, testing, marking (Corrigendum AC:2002 and AC:2005 incorporated)* [A1]

[A1] EN ISO 374-1:2016+A1:2018, *Protective gloves against dangerous chemicals and micro-organisms — Part 1: Terminology and performance requirements for chemical risks (ISO 374-1:2016+A1:2018)* [A1]

EN 455-1:2000, *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* [A1]

[A1] EN 455-3:2015, *Medical gloves for single use — Part 3: Requirements and testing for biological evaluation* [A1]

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

EN 1618:1997, *Catheters other than intravascular catheters — Test methods for common properties*

[A1] *Deleted tex* [A1/]*t* [A1]

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

〈A1〉 EN 13718-1:2014+A1:2020, *Medical vehicles and their equipment — Air ambulances — Part 1: Requirements for medical devices used in air ambulances* 〈A1〉

〈A1〉 EN 13976-1:2018, *Rescue systems — Transportation of incubators — Part 1: Interface conditions* 〈A1〉

〈A1〉 EN 13976-2:2018, *Rescue systems — Transportation of incubators — Part 2: System requirements* 〈A1〉

EN 14605:2005+A1:2009, *Protective clothing against liquid chemicals — Performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])*

〈A1〉 *Deleted text* 〈A1〉

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

〈A1〉 *Deleted text* 〈A1〉

〈A1〉 EN 60601-2-24:2015, *Medical electrical equipment — Part 2-24: Particular requirements for basic safety and essential performance of infusion pumps and controllers (IEC 60601-2-24:2012)* 〈A1〉

〈A1〉 EN 60601-2-34:2014, *Medical electrical equipment — Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment (IEC 60601-2-34:2011)* 〈A1〉

〈A1〉 EN 80601-2-30:2010+A1:2015, *Medical electrical equipment — Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers (IEC 80601-2-30:2009 + Corrigendum Jan. 2010 + A1:2013)* 〈A1〉

〈A1〉 EN ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets (ISO 5356-1:2015)* 〈A1〉

〈A1〉 EN ISO 5359:2014+A1:2017, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases (ISO 5359:2014+Amd1:2017)* 〈A1〉

〈A1〉 EN ISO 5361:2016, *Anaesthetic and respiratory equipment — Tracheal tubes and connectors (ISO 5361:2016)* 〈A1〉

〈A1〉 EN ISO 5364:2016, *Anaesthetic and respiratory equipment — Oropharyngeal airways (ISO 5364:2016)* 〈A1〉

〈A1〉 EN ISO 5366:2016, *Anaesthetic and respiratory equipment — Tracheostomy tubes and connectors (ISO 5366:2016)* 〈A1〉

EN ISO 5367:2014, *Anaesthetic and respiratory equipment — Breathing sets and connectors (ISO 5367:2014)*

〈A1〉 EN ISO 6009:2016, *Hypodermic needles for single use — Colour coding for identification (ISO 6009:2016)* 〈A1〉

EN ISO 7376:2009, *Anaesthetic and respiratory equipment — Laryngoscopes for tracheal intubation (ISO 7376:2009)*

[A1] EN ISO 7396-1:2016, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum (ISO 7396-1:2016)* [A1]

EN ISO 7396-2:2007, *Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems (ISO 7396-2:2007)*

[A1] EN ISO 7864:2016, *Sterile hypodermic needles for single use — Requirements and test methods (ISO 7864:2016)* [A1]

[A1] EN ISO 7886-1:2018, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use (ISO 7886 1:2017)* [A1]

EN ISO 7886-2:1997, *Sterile hypodermic syringes for single use — Part 2: Syringes for use with power-driven syringe pumps (ISO 7886-2:1996)*

[A1] EN ISO 8537:2016, *Sterile single-use syringes, with or without needle, for insulin (ISO 8537:2016)* [A1]

EN ISO 9170-1:2008, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum (ISO 9170-1:2008)*

EN ISO 9360-1:2009, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml (ISO 9360-1:2000)*

[A1] EN ISO 10079-1:2015, *Medical suction equipment — Part 1: Electrically powered suction equipment (ISO 10079 1:2015)* [A1]

EN ISO 10079-2:2014, *Medical suction equipment — Part 2: Manually powered suction equipment (ISO 10079-2:2014)*

EN ISO 10079-3:2014, *Medical suction equipment — Part 3: Suction equipment powered from a vacuum or positive pressure gas source (ISO 10079-3:2014)*

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 10524-2:2006, *Pressure regulators for use with medical gases — Part 2: Manifold and line pressure regulators (ISO 10524-2:2005)*

[A1] EN ISO 10524-3:2006+A1:2013, *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves (ISO 10524-3:2005+Amd1:2013)* [A1]

EN ISO 10524-4:2008, *Pressure regulators for use with medical gases — Part 4: Low-pressure regulators (ISO 10524-4:2008)*

[A1] EN ISO 10555-1:2013+A1:2017, *Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements (ISO 10555-1:2013+Amd1:2017)* [A1]

EN ISO 10555-3:2013, *Intravascular catheters — Sterile and single-use catheters — Part 3: Central venous catheters (ISO 10555-3:2013)*

EN ISO 10555-5:2013, *Intravascular catheters — Sterile and single-use catheters — Part 5: Over-needle peripheral catheters (ISO 10555-5:2013)*

〈A1〉 EN ISO 11070:2014+A1:2018, *Sterile single-use intravascular introducers, dilators and guidewires (ISO 11070:2014+Amd1:2018)* 〈A1〉

EN ISO 13688:2013, *Protective clothing — General requirements (ISO 13688:2013)*

EN ISO 15002:2008, *Flow-metering devices for connection to terminal units of medical gas pipeline systems (ISO 15002:2008)*

EN ISO 18777:2009, *Transportable liquid oxygen systems for medical use — Particular requirements (ISO 18777:2005)*

〈A1〉 EN ISO 19054:2006+A1:2016, *Rail systems for supporting medical equipment (ISO 19054:2005+Amd1:2016)* 〈A1〉

EN ISO 23328-1:2008, *Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance (ISO 23328-1:2003)*

EN ISO 23328-2:2009, *Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects (ISO 23328-2:2002)*

〈A1〉 EN ISO 80601-2-55:2018, *Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 80601-2-55:2018)* 〈A1〉

〈A1〉 EN ISO 80601-2-56:2017, *Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement (ISO 80601-2-56:2017)* 〈A1〉

EN ISO 80601-2-61:2011, *Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO 80601-2-61:2011)*

EN ISO 81060-1:2012, *Non-invasive sphygmomanometers — Part 1: Requirements and test methods for non-automated measurement type (ISO 81060-1:2007)*

EN ISO 81060-2:2014, *Non-invasive sphygmomanometers — Part 2: Clinical investigation of automated measurement type (ISO 81060-2:2013)*

〈A1〉 EN 60601-1-12:2015, *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〉

〈A1〉 EN ISO 80369-7:2017, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications (ISO 80369-7:2016, Corrected version 2016-12-01)* 〈A1〉

〈A1〉 EN ISO 80601-2-12:2011+AC:2011, Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators (ISO/IEC 80601-2-12:2011+Cor:2011) 〈A1〉

〈A1〉 ISO 7137:1995, *Aircraft — Environmental conditions and test procedures for airborne equipment* 〈A1〉

European Aviation Safety Agency (EASA) Certification Specifications CS-23, *Normal, Utility, Aerobatic, and Commuter Category Aeroplanes*

European Aviation Safety Agency (EASA) Certification Specifications CS-25, *Large Aeroplanes*

European Aviation Safety Agency (EASA) Certification Specifications CS-27, *Small Rotorcraft*

European Aviation Safety Agency (EASA) Certification Specifications CS-29, *Large Rotorcraft*