NSAI
Standards

Irish Standard
I.S. EN 13718-1:2014

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

I.S. EN 13718-1:2014

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:	*Published:*
EN 13718-1:2014	2014-09-17

This document was published under the authority of the NSAI and comes into effect on:	ICS number:
2014-10-04	11.040.01 11.160 49.020
	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

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

This European Standard was approved by CEN on 25 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

Contents

Page

Foreword 3

Introduction 4

1 Scope 5

2 Normative references 5

3 Terms and definitions 6

4 Requirements for medical devices for air ambulances 6
4.1 General 6
4.2 Patient and personnel safety 7
4.3 User interface 7
4.4 Environmental conditions and performance of medical devices intended for use in air ambulances 7
4.4.1 Functional temperature range 7
4.4.2 Humidity 8
4.4.3 Variable atmospheric pressures 8
4.5 Electrically-powered medical devices 8
4.5.1 General 8
4.5.2 Medical devices with 12 V DC power input 8
4.5.3 Medical devices with 24 V DC power input 8
4.5.4 Medical devices with 230 V AC power input 9
4.5.5 Short time voltage drop 9
4.5.6 Internal electrical power source 9
4.5.7 Electromagnetic interference of medical devices 9
4.6 Medical gas supply 9
4.6.1 General 9
4.6.2 Gas leakage 9
4.6.3 Pressure regulators and flow metering devices 9
4.6.4 Pneumatic power 10
4.6.5 Cylinder valves 10
4.6.6 Low pressure hose assemblies 10
4.7 Mechanical strength 10
4.7.1 General 10
4.7.2 Vibration and bump 10
4.7.3 Free fall 10
4.8 Fixation of medical devices in air ambulances 10
4.9 Fire resistance 10
4.10 Information to be supplied by the manufacturer 11

5 Test methods 11
5.1 General 11
5.2 Ambient conditions 11
5.3 Test method for durability of markings and colour coding 11
5.4 Free fall 11

Annex ZA (informative) **Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices** 13

Bibliography 15

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.