Irish Standard
I.S. EN 13718-1:2008

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

I.S. EN 13718-1:2008

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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of an identical text or by endorsement, at the latest by February 2009, and conflicting national standards shall be withdrawn at the latest by February 2009.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.