ILNAS

Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN 13976-2:2018

Rescue systems - Transportation of incubators - Part 2: System requirements

Systèmes de secours - Transport d'incubateurs - Partie 2 : Exigences relatives au système

Rettungssysteme - Inkubatortransport - Teil 2: Anforderungen an das Transportsysteme

06/2018

National Foreword

This European Standard EN 13976-2:2018 was adopted as Luxembourgish Standard ILNAS-EN 13976-2:2018.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
- Foresee future developments
- Participate in technical committee meetings

https://portail-qualite.public.lu/fr/normes-normalisation/participer-normalisation.html

EUROPEAN STANDARD EN 13976-2

NORME EUROPÉENNE

EUROPÄISCHE NORM

June 2018

ICS 11.040.10; 11.160

Supersedes EN 13976-2:2011

English Version

Rescue systems - Transportation of incubators - Part 2: System requirements

Systèmes de sauvetage - Transport d'incubateurs - Partie 2: Exigences relatives au système

Rettungssysteme - Inkubatortransport - Teil 2: Anforderungen an Transportsysteme

This European Standard was approved by CEN on 4 September 2017.

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, Serbia, 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: Rue de la Science 23, B-1040 Brussels

Ref. No. EN 13976-2:2018 E

Contents

Page

European foreword

This document (EN 13976-2:2018) 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 December 2018, and conflicting national standards shall be withdrawn at the latest by December 2019.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN not be held responsible for identifying any or all such patent rights.

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.

This document supersedes EN 13976-2:2011.

The following points represent the most important technical changes in the revision:

a) clarified unclear issues about mass of the transport incubator system;

b) a requirement for the infant restraint system was included.

EN 13976 consists of the following parts, under the general title *Rescue systems — Transportation of incubators*:

— *Part 1: Interface requirements*

— *Part 2: System requirements*

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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

This European Standard gives the requirements for a transport incubator system that will ensure its interchangeability as well as its safe and effective function in different vehicles or crafts. Such systems are essential in allowing the uninterrupted care of infants.

Interface requirements are given in part 1 (EN 13976-1).

1 Scope

This European Standard specifies the requirements for a transport incubator system needed for care and treatment of infants, used in emergency or planned transport.

It specifies the particular requirements needed to ensure the proper function of equipment during transportation (e.g. monitors, respirators, infusion pumps, extra corporeal lung support- (ECLS-) systems, gas supply) and to provide safe transportation for infants and operators.

This European Standard also specifies that the equipment or systems shall not interfere with the functions of the road and air ambulance providing transportation.

This European Standard does not give requirements for the vehicles, crafts, devices or incubators as such, these requirements are found in other standards. However, transport incubators are normally combined with other equipment to form a "transport incubator system".

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 1789:2007+A2:2014, *Medical vehicles and their equipment — Road ambulances*

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

EN 1865-2:2010+A1:2015, *Patient handling equipment used in road ambulances — Part 2: Power assisted stretcher*

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

EN 13718-2:2015, *Medical vehicles and their equipment — Air ambulances — Part 2: Operational and technical requirements for air ambulances*

EN 13976-1:2018, *Rescue systems — Transportation of incubators — Part 1: Interface requirements*

EN 60529:1991,[1] *Degrees of protection provided by enclosures (IP Code) (IEC 60529:1989 + A1:1999 + A2:2013)*

EN 60601-1:2006,[2] *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005+Cor.:2006+Cor.:2007+A1:2012)*

EN 60601-1-2:2015, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests (IEC 60601-1-2:2014)*

[1] As impacted by EN 60529:1991/corrigendum May 1993, EN 60529:1991/A1:2000, EN 60529:1991/A2:2013 and EN 60529:1991/AC:2016-2.

[2] As impacted by EN 60601-1:2006/corrigendum Mar. 2010, EN 60601-1:2006/A1:2013, EN 60601-1:2006/A1:2013/AC:2014 and EN 60601-1:2006/A12:2014