SLOVENSKI STANDARD
SIST EN 13718-2:2015/oprA1:2018

01-maj-2018

Ambulantna vozila in njihova oprema - Ambulantna zračna vozila - 2. del: Operativne in tehnične zahteve za ambulantna zračna vozila - Dopolnilo A1

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

Medizinische Fahrzeuge und ihre Ausrüstung - Luftfahrzeuge zum Patiententransport - Teil 2: Operationelle und technische Anforderungen an Luftfahrzeuge zum Patiententransport

Véhicules sanitaires et leur équipement - Ambulances aériennes - Partie 2 : Exigences opérationnelles et techniques pour les ambulances aériennes

Ta slovenski standard je istoveten z: **EN 13718-2:2015/prA1**

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ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general
11.160	Prva pomoč	First aid
49.020	Letala in vesoljska vozila na splošno	Aircraft and space vehicles in general

SIST EN 13718-2:2015/oprA1:2018 **en,fr,de**

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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EN 13718-2:2015

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ICS 11.040.01; 11.160; 49.020

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 draft amendment is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 239.

This draft amendment A1, if approved, will modify the European Standard EN 13718-2:2015. If this draft becomes an amendment, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration.

This draft amendment was established by CEN 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.

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European foreword

This document (EN 13718-2:2015/prA1:2018) has been prepared by Technical Committee CEN/TC 239 “Rescue systems”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

This document has been prepared under a standardization request given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive 93/42/EEC.

For relationship with EU Directives, see informative Annex ZA, which is an integral part of EN 13718-2:2015.

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1 Modifications to Clause 2, Normative references

Replace

"EN 3-9:2006, *Portable fire extinguishers — Part 9: Additional requirements to EN 3-7 for pressure resistance of CO2 extinguishers*"

With

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

Replace

"EN 143:2000, *Respiratory protective devices — Particle filters — Requirements, testing, marking*"

With

"EN 143:2000, *Respiratory protective devices — Particle filters — Requirements, testing, marking (Corrigendum AC:2002 and AC:2005 incorporated)*"

Replace

"EN 374-1:2003, *Protective gloves against chemicals and micro-organisms — Part 1: Terminology and performance requirements*"

With

"EN ISO 374-1:2016 *Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks (ISO 374-1:2016)*"

Replace

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

With

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

Replace

"EN 20594-1:1993, *Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements (ISO 594-1:1986)*"

With

"EN 20594-1:1993/A1:1997, *Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements (ISO 594-1:1986)*"

Replace

"EN ISO 5356-1:2004, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets (ISO 5356-1:2004)*"

With

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

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Replace

"EN ISO 5361:2012, *Anaesthetic and respiratory equipment — Tracheal tubes and connectors (ISO 5361:2012)*"

With

"EN ISO 5361:2016, *Anaesthetic and respiratory equipment - Tracheal tubes and connectors (ISO 5361:2016)*"

Replace

"EN ISO 5364:2011, *Anaesthetic and respiratory equipment — Oropharyngeal airways (ISO 5364:2008)*"

With

"EN ISO 5364:2016, *Anaesthetic and respiratory equipment - Oropharyngeal airways (ISO 5364:2016)*"

Replace

"EN ISO 5366-1:2009, *Anaesthetic and respiratory equipment — Tracheostomy tubes — Part 1: Tubes and connectors for use in adults (ISO 5366-1:2000)"*

With

"EN ISO 5366:2016, *Anaesthetic and respiratory equipment - Tracheostomy tubes and connectors (ISO 5366:2016)"*

Replace

"EN ISO 6009:1994, *Hypodermic needles for single use — Colour coding for identification (ISO 6009:1992)"*

With

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

Replace

"EN ISO 7864:1995, *Sterile hypodermic needles for single use (ISO 7864:1993)"*

With

"EN ISO 7864:2016, *Sterile hypodermic needles for single use - Requirements and test methods (ISO 7864:2016)"*

Replace

"EN ISO 8537:2008, *Sterile single-use syringes, with or without needle, for insulin (ISO 8537:2007)"*

With

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

Replace

"EN ISO 10079-1:2009, *Medical suction equipment — Part 1: Electrically powered suction equipment — Safety requirements (ISO 10079-1:1999)"*

With

"EN ISO 10079-1:2015, *Medical suction equipment - Part 1: Electrically powered suction equipment (ISO 10079-1:2015)"*

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2 Modifications to Clause 4, General requirements for air ambulances

In 4.3, add as a new and final paragraph

"If the air ambulance is intended to carry a transport incubator system it shall have a four pole outlet as specified in prEN 13976-1:2016 Clause 4.2.3 Figure 3.

In 4.7 add as a new and last paragraph

"If the air ambulance is intended to carry a transport incubator system which is to be interchangeable between road or air ambulances it shall have means for complying with a four pole connector as specified in prEN 13976-1:2016 Clause 4.21.3 Figure 3. This can be done by integrated rails in the floor or by using an interface."

3 Modification to Annex A, Medical devices in air ambulances

In Table A.1, replace all references to

"EN 1865-1:2010"

With

"EN 1865-1:2010+A1:2015".

In Table A.3, replace reference to

"EN ISO 5356-1:2004"

With

"EN ISO 5356-1:2015".

In Table A.3, row Endotracheal tubes with connectors, replace

"EN ISO 5366-1:2009"

With

"EN ISO 5366-1:2016".

In Table A.3, row Endotracheal tubes with connectors, replace

"EN ISO 5361:2012"

With

"EN ISO 5361:2016".

In Table A.3, row Oropharyngeal airways, replace

"EN ISO 5364:2011"

With

"EN ISO 5364:2016".

In Table A.5, row Devices for injections and infusions, replace

"EN 20594-1:1993"

With

"EN 20594-1:1993/A1:1993/A1:1997".

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In Table A.5, row Devices for injections and infusions, replace

“EN ISO 7864:1995”

With

“EN ISO 7864:2016”.

In Table A.5, row Devices for injections and infusions, replace

“EN ISO 6009:1994”

With

“EN ISO 6009:2016”.

In Table A.5, row Devices for injections and infusions, replace

“EN ISO 8537:2008”

With

“EN ISO 8537:2016”.

Replace Table A.8 in Clause A.1 with the following

Table A.8 — Transport incubator system equipment

Generic device group	Standards	HEMS	HICAMS	FWAA
Gas supply adapter [a]	EN 13976-1 2017 Clause 4.3.3	1	1	1
[a] This applies if the air ambulance is intended to carry a transport incubator system.				

Delete

"Clause A.2, Additional equipment"

Delete

“Provision for the transportation of incubators shall be in accordance with EN 13976 1:2011 and EN 13976 2:2011.”

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4 Modification to Annex B, Medicinal products and equipment additional to medical devices in air ambulances

In Table B.2, row Fire extinguisher, replace

“EN 3-9:2006”

With

”EN 3-9:2006/AC:2007”.

In Table B.2, row Safety/debris gloves, pairs per crew member, replace

“EN 374-1:2003”

With

“EN 374-1:2016”.