SLOVENSKI STANDARD
SIST EN 13718-1:2015/oprA1:2018

01-maj-2018

Ambulantna vozila in njihova oprema - Ambulantna zračna vozila - 1. del: Zahteve za medicinsko opremo, ki se uporablja v ambulantnih zračnih vozilih - Dopolnilo A1

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

Medizinische Fahrzeuge und ihre Ausrüstung - Luftfahrzeuge zum Patiententransport - Teil 1: Anforderungen an medizinische Geräte, die in Luftfahrzeugen zum Patiententransport verwendet werden

Véhicules sanitaires et leur équipement - Ambulances aériennes - Partie 1: Exigences pour les dispositifs médicaux utilisés dans les ambulances aériennes

Ta slovenski standard je istoveten z: **EN 13718-1:2014/prA1**

ICS:

11.160	Prva pomoč	First aid
49.020	Letala in vesoljska vozila na splošno	Aircraft and space vehicles in general

SIST EN 13718-1:2015/oprA1:2018 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
EN 13718-1:2014

prA1

March 2018

ICS 11.040.01; 11.160; 49.020

Will supersede

English Version

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

Véhicules sanitaires et leur équipement - Ambulances aériennes - Partie 1: Exigences pour les dispositifs médicaux utilisés dans les ambulances aériennes

Medizinische Fahrzeuge und ihre Ausrüstung - Luftfahrzeuge zum Patiententransport - Teil 1: Anforderungen an medizinische Geräte, die in Luftfahrzeugen zum Patiententransport verwendet werden

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 13718-1:2014. 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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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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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 13718-1:2014/prA1:2018 E

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European foreword

This document (EN 13718-1:2014/prA1:2018) has been prepared by Technical Committee CEN/TC 239 “Resuce 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 Directive, see informative Annex ZA, which is an integral part of EN 13718-1:2014.

1 Modifications to Clause 2, Normative references

Replace

*"*EN 13718-2:2008*, Medical vehicles and their equipment — Air ambulances — Part 2: Operational and technical requirements of air ambulances"*

With

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

Replace

*"*EN 60529:1991*, Degrees of protection provided by enclosures (IP Code) (IEC 60529:1989)"*

With

*"*EN 60529:1991/A2:2013*, Degrees of protection provided by enclosures (IP Code) (IEC 60529:1989/A2:2013)"*

Replace

"EN 60601-1 (all parts), *Medical electrical equipment (IEC 60601, all parts)*"

With

"EN 60601-1:2006, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005*)"

Replace

"EN ISO 5359:2008, *Low-pressure hose assemblies for use with medical gases (ISO 5359:2008)*"

With

"EN ISO 5359:2014, *Low-pressure hose assemblies for use with medical gases (ISO 5359:2014)"*

Replace

"EN ISO 10297:2006, *Transportable gas cylinders — Cylinder valves — Specification and type testing (ISO 10297:2006)"*

With

"EN ISO 10297:2014, *Transportable gas cylinders — Cylinder valves — Specification and type testing (ISO 10297:2014*)"

Replace

*"*ISO 7000:2012, Graphical symbols for use on equipment — Registered symbols"

With

*"*ISO 7000:2014*, Graphical symbols for use on equipment — Registered symbols*"

Delete the following references:

"EN 1041:2008+A1:2013, *Information supplied by the manufacturer of medical devices*"

"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)"*

Delete the following footnote

"1) EN 13718-2:2008 is bound to be superseded with a new edition."

2 Modifications to Clause 4, Requirements for medical devices for air ambulances

In 4.3, NOTE 4, replace

"EN 13718-2:2008"

With

"EN 13718-2:2015".

In 4.3, sixth paragraph, delete

"When markings and instructions for the use of medical devices are present they shall conform to EN 1041:2008+A1:2013 and EN ISO 15223-1:2012. Graphical symbols shall be derived from harmonized standards when available. Any other symbols used shall be clear in their intentions, and there shall be a description of the meaning on the label or associated literature."

In 4.5.1 s paragraph, replace

"EN 60529:1991"

With

"EN 60529:1991/A2:2013"

In 4.5.1 NOTE 2, replace

"EN 13718-2:2008"

With

"EN 13718-2:2015".

In 4.6.1 first paragraph, replace

"EN 13718-2:2008"

With

"EN 13718-2:2015".

In 4.6.2 first paragraph, replace

"EN ISO 5359:2008 and EN ISO 10297:2006"

with

"EN ISO 5359:2014 and EN ISO 10297:2014."

In 4.6.5, replace

"EN ISO 10297:2006"

With

"EN ISO 10297:2014".

In 4.6.6 first paragraph, replace

"EN ISO 5359:2008"

With

"EN ISO 5359:2014"

In 4.6.6 second paragraph, replace

"EN ISO 5359:2008, except for 4.4.2.1, shall apply."

With

"EN ISO 5359:2008, except for 4.6.2.1, shall apply."

In 4.7.1 NOTE, replace

"EN 13718-2:2008"

With

"EN 13718-2:2015".

In 4.8 NOTE, replace

"EN 13718-2:2008."

With

"EN 13718-2:2015."

In 4.10 fourth paragraph, delete

"Markings and instructions for the use of medical devices shall conform to EN 1041:2008+A1:2013 and EN ISO 15223-1:2012."

3 Modification to Annex ZA

Replace Annex ZA with the following:

"Annex ZA
(informative)

Relationship between this European standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European standard has been prepared under a Commission's standardization request M/023 concerning the development of European standards related to medical devices to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive, and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table Z0.1 — Correspondence between this European standard and Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements of Directive 93/42/EEC	Clause(s)/subclause(s) of this EN	Remarks/Notes
9.1 first sentence	4.6	Covered as far as connection to the gas installation is concerned
9.2 2nd indent	4.4	Covered for temperature and pressure
12.7.4	4.6	Covered for connections to gas terminals
13.6 (d)	4.10	Covered for maintenance only

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the product(s) falling within the scope of this standard."