SLOVENSKI STANDARD
SIST EN ISO 18777:2005

01-junij-2005

Prenosni sistemi tekoļ ega kisika za medicinsko uporabo ï Posebne zahteve (ISO 18777:2005)

Transportable liquid oxygen systems for medical use - Particular requirements (ISO 18777:2005)

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Flüssigsauerstoffsysteme für medizinische Anwendungen - Besondere Anforderungen (ISO 18777:2005)

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Systemes transportables d'oxygene liquide a usage médical - Exigences particulieres (ISO 18777:2005)

SIST EN ISO 18777:2005
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Ta slovenski standard je istoveten z: **EN ISO 18777:2005**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

SIST EN ISO 18777:2005 **en**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 18777

February 2005

ICS 11.040.99

English version

Transportable liquid oxygen systems for medical use - Particular requirements (ISO 18777:2005)

Systèmes transportables d'oxygène liquide à usage médical - Exigences particulières (ISO 18777:2005)

Flüssigsauerstoffsysteme für medizinische Anwendungen - Besondere Anforderungen (ISO 18777:2005)

This European Standard was approved by CEN on 28 January 2005.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Ref. No. EN ISO 18777:2005: E

SIST EN ISO 18777:2005

Foreword

This document (EN ISO 18777:2005) has been prepared by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI, in collaboration with Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment".

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 August 2005, and conflicting national standards shall be withdrawn at the latest by August 2005.

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.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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ANNEX ZA
(informative)

Relationship between this International Standard and the Essential Requirements of EU Directive 93/42 EEC Medical devices

This International Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide one means of conforming to Essential Requirements of the New Approach Directive 93/42 EEC Medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, 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.

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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Table ZA.1 — Correspondence between this International Standard and Directive 93/42/EEC Medical devices

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Clause(s)/Subclause(s) of this International Standard	Essential Requirements (Ers) of EU Directive 93/42/EEC	Qualifying remarks/Notes
4	All	
5	All	
6	13, 13.2	
6.1	13.1, 13.3, 13.4, 13.5	
6.3	10.2, 10.3, 12.8, 12.9	
6.8	13.1, 13.3, 13.4, 13.6	
6.101	12.9	
7	12.6	
8	12.6	
9	12.6	
10.1	5	
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13	12.6	
14	12.6	
15	12.6	

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18	12.6	
19	12.6	
20	12.6	
21	12.7	
22	12.7	
23	12.7	
24	12.7	
25	12.7	
26	12.7.2, 12.7.3	
27	12.8	
28	12.7	
29	11	
36	9.2, 12.5	
38	13	
39	9.2, 9.3, 12.6, 12.7	
40	9.2, 9.3, 12.6, 12.7	
41	9.2, 9.3, 12.6, 12.7	
42	12.7	
43	9.3, 12.7	
44.3	7.6, 12.6	
44.6	7.6, 12.6	
44.7	8.1	
44.8	7.1, 7.3, 7.5, 9.3	
45	12.7	
46	9, 10, 12.9	
47	12.5	
48	7.1, 7.5	
49	9.2, 12.8	
50	10	
51	10, 12.8	
52	12.1, 12.6, 12.7, 12.8	
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55	9	
56	9	
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56.7	12.2	
57	12.6, 12.7	
58	12.6, 12.7	
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101.2.3	12.8	
101.2.4	12.8	
101.2.6	12.8	
101.2.7	12.2	
101.2.8	9.3, 12.6, 12.8	
101.3	12.3, 12.8	

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INTERNATIONAL STANDARD

ISO 18777

First edition
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Transportable liquid oxygen systems for medical use — Particular requirements

Systèmes transportables d'oxygène liquide à usage médical — Exigences particulières

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 18777 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in collaboration with Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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