ILNAS

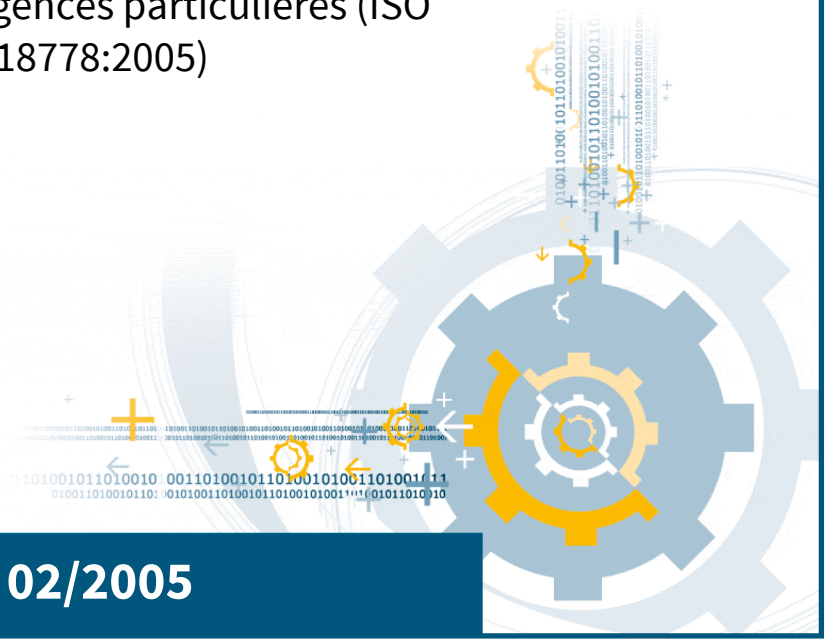
Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN ISO 18778:2005

Respiratory equipment - Infant monitors - Particular requirements (ISO 18778:2005)

Beatmungsgeräte - Überwachungsgeräte für Kleinkinder - Besondere Anforderungen (ISO 18778:2005)

Matériel respiratoire - Moniteurs pour enfants - Exigences particulières (ISO 18778:2005)



02/2005

National Foreword

This European Standard EN ISO 18778:2005 was adopted as Luxembourgish Standard ILNAS-EN ISO 18778:2005.

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
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 18778

February 2005

ICS 11.040.10

English version

Respiratory equipment - Infant monitors - Particular requirements (ISO 18778:2005)

Matériel respiratoire - Moniteurs pour enfants - Exigences particulières (ISO 18778:2005)

Beatmungsgeräte - Überwachungsgeräte für Kleinkinder - Besondere Anforderungen (ISO 18778:2005)

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.

CEN members are the national standards bodies of 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.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN ISO 18778:2005: E

EN ISO 18778:2005 (E)

Foreword

This document (EN ISO 18778:2005) 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.

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.

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

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	
10.2	5	
13	12.6	
14	12.6	
15	12.6	

16	12.6, 12.7	
17	12.6	
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	
53	5	

54	9	
55	9	
56	9	
56.3	9.1	
56.7	12.2	
57	12.6, 12.7	
58	12.6, 12.7	
101.2.1	9.2, 12.8	
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	

INTERNATIONAL STANDARD

ISO 18778

First edition
2005-02-15

Respiratory equipment — Infant monitors — Particular requirements

Matériel respiratoire — Moniteurs pour enfants — Exigences particulières

Reference number
ISO 18778:2005(E)