

Irish Standard I.S. EN ISO 10524-4:2008

Pressure regulators for use with medical gases - Part 4: Lowpressure regulators (ISO 10524-4:2008)

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I.S. EN ISO 10524-4:2008

Incorporating amendments/corrigenda issued since publication:

This standard replaces: I.S. EN 738-4:1999

This standard is based on: EN ISO 10524-4:2008 EN 738-4:1998 Published: 1 June, 2008 9 April, 1999

This Irish Standard was published under the authority of the NSAI and comes into effect on: 6 August, 2008 ICS number: 11.040.10

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Údarás um Chaighdeáin Náisiúnta na hÉireann

I.S. EN ISO 10524-4:2008

EUROPEAN STANDARD

EN ISO 10524-4

NORME EUROPÉENNE EUROPÄISCHE NORM

June 2008

ICS 11.040.10

Supersedes EN 738-4:1998

English Version

Pressure regulators for use with medical gases - Part 4: Lowpressure regulators (ISO 10524-4:2008)

Détendeurs pour l'utilisation avec les gaz médicaux - Partie 4: Détendeurs basse pression (ISO 10524-4:2008)

Druckminderer zur Verwendung mit medizinischen Gasen -Teil 4: Niederdruckminderer (ISO 10524-4:2008)

This European Standard was approved by CEN on 29 May 2008.

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EN ISO 10524-4:2008 (E)

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EN ISO 10524-4:2008 (E)

Foreword

This document (EN ISO 10524-4:2008) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment" the secretariat of which is held by BSI.

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of an identical text or by endorsement, at the latest by December 2008, and conflicting national standards shall be withdrawn at the latest by June 2010.

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

This document supersedes EN 738-4:1998.

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 EC Directive(s).

For relationship with EC 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, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 10524-4:2008 has been approved by CEN as a EN ISO 10524-4:2008 without any modification.

Annex ZA (informative)

Correspondence between this International Standard and Directive 93/42/EEC

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 on 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 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.

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
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5.3.3	4 – 7.1 – 9.2	
5.3.4	3 – 5	
5.3.5	7.1 – 7.2	
5.4	2-3-4	
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5.4.2.1	10.2 – 10.3	
5.4.2.3	10.2	
5.4.3	9.1 – 12.7.4	
5.4.4	9.1 – 12.7.4	
5.4.6	12.7.1	
5.4.7	7.2 – 7.6	
5.4.8	7.5	
5.4.9	7.5 – 9.2 – 12.7.1	
5.4.10.1	12.8.1 – 12.8.2	
5.4.10.2	10.2	



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