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Standards

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

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

## I.S. EN ISO 10524-4:2008

*Incorporating amendments/corrigenda issued since publication:*

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English Version

## Pressure regulators for use with medical gases - Part 4: Low-pressure 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.

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 CEN Management Centre 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 CEN Management Centre has the same status as the official versions.

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**Contents**

Page

**Foreword.....3**

**Annex ZA (informative) Correspondence between this International Standard and Directive  
93/42/EEC.....4**

## **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of an identical text or by endorsement, at the latest by December 2008, and conflicting national standards shall be withdrawn at the latest by June 2010.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
5	1	
5.1	2 - 6	
5.1.2	9.1 - 12.7.4	
5.2	2	
5.3	2	
5.3.1	7.1 – 7.3 – 9.3	
5.3.2	7.3 – 9.3	
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	
5.4.1	9.2	
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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