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RATIFICACIÓN DE DOCUMENTOS EUROPEOS FEBRERO 2012

HOJA DE ANUNCIO

En cumplimiento del punto 11.2.6.4 de las Reglas Internas de CEN/CENELEC Parte 2, se ha otorgado el rango de norma española al Documento Europeo siguiente:

Documento Europeo	Título	Fecha de Disponibilidad
EN ISO 80601-2-55:2011	Equipos electromédicos. Parte 2-55: Requisitos particulares para la seguridad básica y el funcionamiento esencial de los monitores de gas respiratorio (ISO 80601-2-55:2011) (Ratificada por AENOR en febrero de 2012.)	2011-12-15

Este anuncio causará efecto a partir del primer día del mes siguiente al de su publicación en la revista UNE. La correspondiente versión oficial de este documento se encuentra disponible en la sede de AENOR, Calle Génova 6, 28004 MADRID.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80601-2-55

December 2011

ICS 11.040.10

Supersedes EN ISO 21647:2009

English Version

Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 80601-2-55:2011)

Appareils électromédicaux - Partie 2-55: Exigences particulières relatives à la sécurité de base et aux performances essentielles des moniteurs de gaz respiratoires (ISO 80601-2-55:2011)

Medizinische elektrische Geräte - Teil 2-55: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Überwachungsgeräten für Atemgase (ISO 80601-2-55:2011)

This European Standard was approved by CEN on 2 December 2011.

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, 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, Turkey and United Kingdom.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Ref. No. EN ISO 80601-2-55:2011: E

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Foreword

This document (EN ISO 80601-2-55:2011) 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 June 2012, and conflicting national standards shall be withdrawn at the latest by December 2014.

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 ISO 21647:2009.

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.

For relationship with EU Directive, 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, Croatia, 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 80601-2-55:2011 has been approved by CEN as a EN ISO 80601-2-55:2011 without any modification.

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Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU 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 a means to conforming to Essential Requirements of the New Approach Directive 93/42/EEC, Council Directive of 14 June 1993 on the approximation of the laws of the Member States concerning medical devices" (Medical Device Directive).

Once this standard is cited in the Official Journal of the European Union 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 European Standard and Directive 93/42/EEC

Clause(s)/subclause(s) of this European Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
201.11.6.4 to 201.11.6.6	7.2	Only the parts of ER 7.2 relating to safety in use for the patient are addressed
201.11.6.4, 201.11.6.8	7.3	Only the part of the first sentence relating to design is addressed
201.11.6.4	7.5	
201.11.6.5, 201.101	7.6	
201.11.6.6, 201.11.6.7 , 201.105	8.1	The part of ER 8.1 relating to easy handling is not addressed
201.11.6.7	8.4	Validated processes for sterilization are required via the normative references to ISO 11134, ISO 11135, ISO 11137
201.7.2.17.101	8.7	
201.7.2.101, 201.7.2.4.101, 201.7.2.13.101, 201.7.2.17.101, 201.12.1.102, 201.102, 201.103, 208	9.1	
201.9, 201.101, 202, 206	9.2	The 4th indent of ER 9.2 is not addressed

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Table ZA.1 (*continued*)

Clause(s)/subclause(s) of this European Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
201.11	9.3	
201.12.1, 201.101	10.1	
201.7, 201.12.1.103, 201.12.1.104, 206, 208	10.2	
201.7.4.3	10.3	
201.10	11.1.1	
202	11.3.1	
201.14	12.1	
201.14	12.1 a)	
201.11.8.101, 208	12.2	
201.11.8.101, 208	12.3	
208	12.4	
202	12.5	
201.8	12.6	
201.9	12.7.1	
201.9	12.7.2	
201.9	12.7.3	
201.8, 201.15, 201.103	12.7.4	
201.11	12.7.5	
201.104	12.8.2	Only the first sentence of ER 12.8.2 is covered
201.7, 201.12.1, 206	12.9	
201.7, 201.7.2.4.101, 201.7.2.13.101, 201.7.2.17.101, 201.7.2.101	13.1	
201.7, 201.7.2.3, 201.7.2.13.101, 201.7.2.17.101, 201.7.2.101	13.2	
201.7.9.1	13.3 a)	
201.7, 201.7.2.17.101, 201.7.2.101	13.3 b)	
201.7, 201.7.2.17.101	13.3 c)	
201.7.2.17.101, 201.7.2.101	13.3 d)	Is only covered if the batch number is preceded by the word LOT
201.7.2.101	13.3 e)	
201.7.2.4.101, 201.7.2.17.101 b)	13.3 f)	Distinction between “single use“ and “single-patient use” taken into account
201.7.2.101 a)	13.3 i)	
201.7, 201.7.2	13.3 j)	

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Table ZA.1 (*continued*)

Clause(s)/subclause(s) of this European Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
201.7, 201.7.9.2.2.101	13.3 k)	
201.7, 201.7.2.17 a)	13.3 m)	Presumption of conformity is only provided if symbols 5.21 to 5.24 are utilized
201.7.9.2.1.101 a), 201.7.2.17.101, 201.7.2.101	13.4	
201.7.2.17.101 a), 201.7.2.101 b)	13.5	Is only covered if the batch number is preceded by the word LOT
201.7, 201.7.9.1, 201.7.9.2.1.101, 201.7.9.2.2.101	13.6 a)	
201.7, 201.7.9.2.1.101, 201.7.9.2.2.101, 201.7.9.2.9.101 c), 201.7.9.2.9.101 d)	13.6 b)	
201.7, 201.7.9.2.2.101, 201.7.9.2.5.101, 201.7.9.2.9.101 e)	13.6 c)	
201.7, 201.7.9.2.13.101	13.6 d)	
201.7, 201.7.9.2.9.101 g), , 201.7.9.2.9.101 k)	13.6 f)	
201.7.9.2.14.101 b)	13.6 g)	
201.7, 201.7.9.2.9.101 l) , 201.7.9.2.14.101 b)	13.6 h)	
201.7	13.6 i)	
201.7.9.2.1.101 c)	13.6 j)	
201.7	13.6 k)	
201.7	13.6 l)	
201.7, 201.7.9.2.14.101 c), 201.7.9.2.15.101	13.6 n)	
201.12.1.101.1	13.6 p)	
201.7.9.2.9.101 m)	13.6 q)	

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For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC, the following Table ZA.2 details the relevant essential health and safety requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than essential requirements of Directive 93/42/EEC along with the corresponding clauses of this International Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.2 — Relevant Essential Requirements from Directive 2006/42/EC on machinery that are addressed by this European Standard
(according to article 3 of amended Directive 93/42/EEC)

Clause(s)/subclause(s) of this European Standard	Essential health and safety requirements (ERs) of EU Directive 2006/42/EC	Qualifying remarks/Notes
201.7, 201.12.1	1.1.4	Only the first sentence of EHSR 1.1.4 is addressed
201.12.1, 201.12.1.104, 206, 208.6.5.1, 208.6.6.2.101	1.2.2	Only the parts of EHST 1.2.2 relevant to the RGM are addressed
201.7.2.101 d), 201.7.2.101 e), 201.7.2.101 f), 201.7.2.101 g) 201.7.2.101 h), 201.103, 201.105	1.5.4	
201.7	1.6.2	
201.8	1.6.3	
201.7, 201.7.2.101 i)	3.6.2	

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

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