



National Standards Authority of Ireland

IRISH STANDARD

I.S. EN 15424:2007

ICS 11.080.01

**STERILIZATION OF MEDICAL DEVICES - LOW  
TEMPERATURE STEAM AND  
FORMALDEHYDE - REQUIREMENTS FOR  
DEVELOPMENT, VALIDATION AND ROUTINE  
CONTROL OF A STERILIZATION PROCESS  
FOR MEDICAL DEVICES**

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*This Irish Standard was  
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28 May 2007*

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EUROPEAN STANDARD

**EN 15424**

NORME EUROPÉENNE

EUROPÄISCHE NORM

April 2007

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ICS 11.080.01

English Version

## Sterilization of medical devices - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices

Stérilisation des dispositifs médicaux - Développement, validation et contrôle de routine des procédés de stérilisation - Vapeur d'eau à basse température et au formaldéhyde

Sterilisation von Medizinprodukten - Niedertemperatur-Dampf-Formaldehyd - Anforderungen an die Entwicklung, Validierung und Routineüberwachung von Sterilisationsverfahren für Medizinprodukte

This European Standard was approved by CEN on 17 February 2007.

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EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
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## **EN 15424:2007 (E)**

### **Foreword**

This document (EN 15424:2007) has been prepared by Technical Committee CEN/TC 204 "Sterilization of medical devices", 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of an identical text or by endorsement, at the latest by October 2007, and conflicting national standards shall be withdrawn at the latest by October 2007.

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, 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 United Kingdom.

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