

---

---

**Sterilization of health care products —  
Chemical indicators —**

**Part 5:  
Class 2 indicators for Bowie and Dick-  
type air removal tests**

*Stérilisation des produits de santé — Indicateurs chimiques —*

*Partie 5: Indicateurs de Classe 2 pour l'essai de Bowie et Dick  
d'enlèvement d'air*



Reference number  
ISO 11140-5:2007(E)

**PDF disclaimer**

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

© ISO 2007

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Published in Switzerland

# Contents

Page

<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>v</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 General requirements</b> .....	<b>2</b>
<b>5 Indicator system</b> .....	<b>2</b>
<b>5.1 Format</b> .....	<b>2</b>
<b>5.2 Performance</b> .....	<b>2</b>
<b>6 Indicator</b> .....	<b>3</b>
<b>6.1 Format</b> .....	<b>3</b>
<b>6.2 Performance</b> .....	<b>3</b>
<b>7 Packaging and labelling</b> .....	<b>4</b>
<b>8 Quality assurance</b> .....	<b>4</b>
<b>9 Sampling conditioning</b> .....	<b>4</b>
<b>Annex A (normative) Determination of the degree of contrast between the colour of the substrate and the indicator agent</b> .....	<b>5</b>
<b>Annex B (normative) Method of determining uniform colour change on exposure to saturated steam</b> .....	<b>6</b>
<b>Annex C (normative) Method for determining indicator colour change on exposure to dry heat</b> .....	<b>7</b>
<b>Annex D (normative) Method for determining transfer of indicator agent to standard test pack</b> .....	<b>8</b>
<b>Annex E (normative) Standard test pack</b> .....	<b>9</b>
<b>Annex F (normative) Method of determining non-uniform colour change on exposure to a standard fault condition</b> .....	<b>10</b>
<b>Annex G (normative) Steam exposure apparatus</b> .....	<b>11</b>
<b>Bibliography</b> .....	<b>12</b>

## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 11140-5 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 11140-5:2000), which has been technically revised.

ISO 11140 consists of the following parts, under the general title *Sterilization of health care products — Chemical indicators*:

- *Part 1: General requirements*
- *Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test*
- *Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration*
- *Part 5: Class 2 indicators for Bowie and Dick-type air removal tests*