

# INTERNATIONAL STANDARD

**ISO**  
**11140-1**

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**AMENDMENT 1**  
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## **Sterilization of health care products — Chemical indicators —**

### **Part 1: General requirements**

#### **AMENDMENT 1**

*Stérilisation des produits de santé — Indicateurs chimiques —*

*Partie 1: Prescriptions générales*

*AMENDEMENT 1*



Reference number  
ISO 11140-1:1995/Amd.1:1998(E)

## 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.

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.

Amendment 1 to International Standard ISO 11140-1:1995 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

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International Organization for Standardization  
Case postale 56 • CH-1211 Genève 20 • Switzerland  
Internet iso@iso.ch

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# Sterilization of health care products — Chemical indicators —

## Part 1: General requirements

### AMENDMENT 1

#### *Page 3*

Include a new subclause after 5.8, as follows:

**5.9** With the exception of irradiation indicators, when tests are performed with the equipment and procedures specified in ISO 11140-2, the results are deemed to be adequate for determining compliance with the requirements specified in this part of ISO 11140.

#### *Pages 6 and 7*

Add the following note to tables 1, 2 and 3:

NOTE The limiting values in the column labelled 'saturation' refer to the steam supply to the chamber.