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

Part 2:
Test equipment and methods

*Stérilisation des produits de santé — Indicateurs chimiques —
Partie 2: Appareillage et méthodes d'essai*



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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.

International Standard ISO 11140-2 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

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

- *Part 1: General requirements*
- *Part 2: Test equipment and methods*
- *Part 3: Steam penetration test with user-assembled and preassembled test packs*
- *Part 4: Class 2 indicators for air-removal test*

Introduction

To test the performance of chemical indicators, with the exception of irradiation indicators, specific test equipment is required. This part of ISO 11140 specifies the performance requirements for the test equipment to be used to establish the response to the essential physical parameters. Irradiation indicators are generally tested in irradiation facilities.

The performance tolerances for equipment given in this part of ISO 11140 are intended to be suitable for testing any of the classes of indicator specified in ISO 11140-1. Equipment operating with wider tolerances may be suitable for specific applications.