

INTERNATIONAL STANDARD

ISO
11140-1

First edition
1995-07-15

AMENDMENT 1
1998-12-01

Sterilization of health care products — Chemical indicators —

Part 1: General requirements

AMENDMENT 1

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Sterilisation des produits de santé — Indicateurs chimiques —

Partie 1: Prescriptions générales

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Foreword

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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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Printed in Switzerland

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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.

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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.

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ICS 11.080

Descriptors: health care products, medical equipment, sterilization, chemical indicators, tests, performance tests, test equipment, equipment specifications, performance.

Price based on 1 page
