



NSAI
Standards

Irish Standard
S.R. CEN ISO/TS 11135-2:2008

Sterilization of health care products - Ethylene oxide - Part 2: Guidance on the application of ISO 11135-1 (ISO/TS 11135-2:2008)

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S.R. CEN ISO/TS 11135-2:2008

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TECHNICAL SPECIFICATION
SPÉCIFICATION TECHNIQUE
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CEN ISO/TS 11135-
2:2008/AC

ICS 11.080.01

April 2009
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English version
Version Française
Deutsche Fassung

Sterilization of health care products - Ethylene oxide - Part 2: Guidance on
the application of ISO 11135-1 (ISO/TS 11135-2:2008/Cor 1:2009)

Stérilisation des produits de santé - Oxyde
d'éthylène - Partie 2: Directives relatives à
l'application de l'ISO 11135-1 (ISO/TS
11135-2:2008/Cor 1:2009)

Sterilisation von Produkten für die
Gesundheitsfürsorge - Ethylenoxid - Teil 2:
Leitfaden zur Anwendung von ISO 11135-1
(ISO/TS 11135-2:2008/Cor 1:2009)

This corrigendum becomes effective on 8 April 2009 for incorporation in the three official language
versions of the TS.

Ce corrigendum prendra effet le 8 avril 2009 pour incorporation dans les trois versions linguistiques
officielles de la TS.

Die Berichtigung tritt am 8.April 2009 zur Einarbeitung in die drei offiziellen Sprachfassungen der TS
in Kraft.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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S.R. CEN ISO/TS 11135-2:2008/AC:2009
CEN ISO/TS 11135-2:2008/AC:2009 (E)

Endorsement notice

The text of CEN ISO/TS 11135-2:2008/Cor.1:2009 has been approved by CEN as a European Corrigendum without any modification.



**INTERNATIONAL STANDARD ISO/TS 11135-2:2008
TECHNICAL CORRIGENDUM 1**

Published 2009-02-15

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**Sterilization of health care products — Ethylene oxide —
Part 2:
Guidance on the application of ISO 11135-1**

TECHNICAL CORRIGENDUM 1

Stérilisation des produits de santé — Oxyde d'éthylène —

Partie 2: Directives relatives à l'application de l'ISO 11135-1

RECTIFICATIF TECHNIQUE 1

Technical Corrigendum 1 to ISO/TS 11135-2:2008 was prepared by Technical Committee ISO/TC 198,
Sterilization of health care products

Page 34, Equation (A.15)

The third line from the bottom of the page should read

$$= \frac{1}{0,74 \pm 1,96 \sqrt{0,74 \times 0,005\ 2}} = \frac{1}{0,74 \pm 1,96 \sqrt{0,003\ 85}} = \frac{1}{0,74 \pm 1,96 \times (0,062)} = \frac{1}{0,74 \pm 0,122}$$

TECHNICAL SPECIFICATION
SPÉCIFICATION TECHNIQUE
TECHNISCHE SPEZIFIKATION

CEN ISO/TS 11135-2

August 2008

ICS 11.080.01

English Version

**Sterilization of health care products - Ethylene oxide - Part 2:
Guidance on the application of ISO 11135-1 (ISO/TS 11135-
2:2008)**

Stérilisation des produits de santé - Oxyde d'éthylène -
Partie 2: Directives relatives à l'application de l'ISO 11135-
1 (ISO/TS 11135-2:2008)

Sterilisation von Produkten für die Gesundheitsfürsorge -
Ethylenoxid - Teil 2: Leitfaden zur Anwendung von ISO
11135-1 (ISO/TS 11135-2:2008)

This Technical Specification (CEN/TS) was approved by CEN on 8 June 2008 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

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