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NORME EUROPÉENNE
EUROPÄISCHE NORM

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May 2007

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English Version

Sterilization of health care products - Ethylene oxide - Part 1:
Requirements for development, validation and routine control of
a sterilization process for medical devices (ISO 11135-1:2007)

Stérilisation des produits de santé - Oxyde d'éthylène -
Partie 1: Exigences de développement, de validation et de
contrôle de routine d'un processus de stérilisation pour des
dispositifs médicaux (ISO 11135-1:2007)

Sterilisation von Produkten für die Gesundheitsfürsorge -
Ethylenoxid - Teil 1: Anforderungen an die Entwicklung, :
Validierung und Lenkung der Anwendung eines
Sterilisationsverfahrens für Medizinprodukte (ISO
11135:2007)

This European Standard was approved by CEN on 13 April 2007.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Foreword

Endorsement notice

Annex ZA

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC Medical devices

Table ZA — Correspondence between this European Standard and Directive 93/42/EEC Medical devices

Clause(s)/Sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 90/385/EEC	Essential Requirements (ERs) of Directive 93/42/EEC	Essential Requirements (ERs) of Directive 98/79/EC	Qualifying remarks/Notes

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**ISO
11135-1**

**Sterilization of health care products —
Ethylene oxide —**

**Requirements for development, validation
and routine control of a sterilization
process for medical devices**

Stérilisation des produits de santé — Oxyde d'éthylène —



PDF disclaimer

ISO 11135-1:2007(E)



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Foreword

Sterilization of health care products —

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Introduction

Sterilization of health care products — Ethylene oxide —

Requirements for development, validation and routine control of a sterilization process for medical devices

1 Scope

Attention is drawn to national or regional requirements for designating medical devices as "sterile". See for

2 Normative references

Measurement management systems — Requirements for measurement processes and measuring

Biological evaluation of medical devices — Part 1: Evaluation and testing

Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals

Sterilization of health care products — Biological indicators — Part 1: General

of health care products — Biological indicators — Part 2: Biological indicators

Sterilization of health care products — Chemical indicators — Part 1: General requirements

Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population

Sterilization of medical devices — Microbiological methods — Part 2: Tests of sterility performed in

Medical devices — Quality management systems — Requirements for regulatory purposes

Sterilization of health care products — Biological indicators — Guidance for the selection, use and

Sterilization of health care products — General requirements for characterization of a

3 Terms and definitions

3.1 aeration

3.2
aeration area

3.3
bioburden

3.4
biological indicator

3.5
calibration

3.6
chemical indicator

3.7
conditioning

3.8
D value
value

3.9
development

3.10
establish

3.11
ethylene oxide injection time

3.12
exposure time

3.13
fault

3.14
flushing

3.15
fractional cycle

3.16
half cycle

3.17
health care product

3.18
installation qualification
IQ

**3.19
medical device**

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**3.20
microorganism**

**3.21
operational qualification
OQ**

**3.22
overkill**

**3.23
parametric release**

3.24
performance qualification
PQ

3.25
preconditioning

3.26
process challenge device
PCD

3.27
process parameter

3.28
process variable

3.29
product

3.30
product load volume

3.31
recognized culture collection

3.32
reference microorganism

**3.33
requalification**

**3.34
services**

**3.35
specify**

**3.36
Spore Log Reduction
SLR**

reported as "greater than" log No.

**3.37
sterile**

**3.38
sterility**

3.39
sterility assurance level
SAL

3.40
sterilization

3.41
sterilization cycle

3.42
sterilization load

3.43
sterilization process

3.44
sterilizing agent

3.45
survivor curve

3.46
test of sterility

3.47
usable chamber volume

3.48
validation

4 Quality management systems

4.1 Documentation

4.1.1

4.1.2

4.2 Management responsibility

4.2.1

4.2.2

4.3 Product realization

4.3.1

4.3.2

4.3.3

4.4 Measurement, analysis and improvement — Control of nonconforming product

5 Sterilizing agent characterization

5.1 Sterilizing agent

5.2 Microbicidal effectiveness

5.3 Material effects

5.4 Environmental considerations

5.4.1

5.4.2

6 Process and equipment characterization

6.1 Process characterization

6.1.1

6.1.2

6.1.3

6.1.4

6.1.5

6.1.6

6.2 Equipment characterization

6.2.1

6.2.2

6.2.3

6.2.4

7 Product definition

7.1 General

7.1.1

7.1.2

7.1.3 -

7.1.4

7.1.5 -

7.2 Product safety and performance

7.2.1

7.2.2

7.2.3

7.2.4

7.3 Microbiological quality

7.3.1

7.3.2

7.4 Documentation

8 Process definition

8.1

8.2

8.3

8.4

8.5

8.6

8.7

8.8

8.9

9 Validation

9.1 Installation qualification

9.1.1

9.1.2

9.1.3

9.1.4

9.1.5

9.1.6

9.2 Operational qualification

9.2.1

9.2.2

9.3 Performance qualification

9.3.1 General

9.3.1.1

9.3.1.2

9.3.1.3

9.3.1.4

9.3.1.5

9.3.2 Performance qualification — Microbiological

9.3.2.1

9.3.2.2

9.3.2.3

9.3.2.4

9.3.2.5

9.3.3 Performance qualification — Physical

9.3.3.1

9.3.3.2

9.4 Varying load configurations

9.5 Review and approval of validation

9.5.1

9.5.2

9.5.3

9.5.4

9.5.5

9.5.6

10 Routine monitoring and control

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11 Product release from sterilization

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12 Maintaining process effectiveness

12.1 General

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12.2 Maintenance of equipment

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Procedures. All procedures shall follow manufacturers' recommendations as well as any pertinent national,

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12.3 Requalification

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12.4 Assessment of change

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Annex A

Determination of lethal rate of the sterilization process — Biological indicator/bioburden approach

A.1 General

A.2 Procedure

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2

A.3 Process lethality determination

A.3.1 Direct enumeration

A.3.1.1

A.3.1.2

A.3.2 Fraction-negative method using Holcomb-Spearman Karber procedure (HSKP)

A.3.3 Fraction-negative method using Stumbo Murphy Cochran procedure (SMCP)

Annex B

Conservative determination of lethal rate of the sterilization process — Overkill approach

B.1 General

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B.2 Procedure

B

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B.2.2

B

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B

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B

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Annex C

General guidance

C.1 Scope

C.2 Normative references

C.3 Terms and definitions

C.4 Quality management systems

C.4.1 Documentation

C.4.2 Management responsibility

C.4.3 Product realization

C.4.3.1

C.4.3.2

C.4.3.3

C.4.4 Measurement, analysis and improvement — Control of non-conforming product

C.5 Sterilizing agent characterization

C.5.1 Sterilizing agent

C.5.2 Microbicidal effectiveness

C.5.3 Materials effects

C.5.4 Environmental considerations

C.5.4.1

C.5.4.2

C.6 Process and equipment characterization

C.6.1 Process characterization

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C.6.2 Equipment characterization

C.6.2.1

C.6.2.2

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C.6.2.3

C.6.2.4

C.7 Product definition

C.7.1 General

C.7.1.1

C.7.1.2

C.7.1.3

C.7.1.4

C.7.1.5

C.7.2 Product safety and performance

C.7.3 Microbiological quality

C.7.4 Documentation

C.8 Process definition

C.9 Validation

C.9.1 Installation qualification

C.9.2 Operational qualification

C.9.3 Performance qualification

C.9.3.1 General

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-
-
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C.9.3.2 Performance qualification — Microbiological

C.9.3.3 Performance qualification — Physical

C.9.3.3.1

C.9.3.3.2

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C.9.4 Varying load configurations

different materials and packaging, and varying physical mass that represents the “worst case” challenge to the

C.9.5 Review and approval of validation

C.9.5.1

C.9.5.2

C.9.5.3

C.9.5.4

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C.9.5.5

C.9.5.6

C.10 Routine monitoring and control

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C.11 Product release from sterilization

C.12 Maintaining process effectiveness

C.12.1 General

C.12.2 Maintenance of equipment

C.12.3 Requalification

C.12.3.1

C.12.3.2

C.12.3.3

C.12.3.4

C.12.3.5

C-12-3-6

C.12.3.7

C-12.3.8

C.12.4 Assessment of change

Table C.1 — Examples of minimum recommended number of temperature sensors

Table C.2 — Examples of minimum recommended number of humidity sensors

Table C.3 — Examples of minimum recommended number of BI/PCDs

C.13 Guidance on Annex A — Determination of lethal rate of the sterilization process — Biological indicator/bioburden approach

's population regardless of the

C.14 Guidance on Annex B — Conservative determination of lethal rate of the sterilization process — Overkill approach

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