

English Version

**Sterilization of health care products - Moist heat - Part 1:  
Requirements for the development, validation and routine  
control of a sterilization process for medical devices (ISO 17665-  
1:2006)**

Stérilisation des produits de santé - Chaleur humide -  
Partie 1: Exigences pour le développement, la validation et  
le contrôle de routine d'un procédé de stérilisation des  
dispositifs médicaux (ISO 17665-1:2006)

Sterilisation von Produkten für die Gesundheitsfürsorge -  
Feuchte Hitze - Teil 1: Anforderungen an die Entwicklung,  
Validierung und Lenkung der Anwendung eines  
Sterilisationsverfahrens für Medizinprodukte (ISO 17665-  
1:2006)

This European Standard was approved by CEN on 14 July 2006.

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

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

Foreword

Endorsement notice

# ISO 17665-1

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## **Sterilization of health care products — Moist heat —**

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

Stérilisation des produits de santé — Chaleur humide —





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Foreword

Sterilization of health care products — Moist

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Introduction







# **Sterilization of health care products — Moist heat —**

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

### **1 Scope**

#### **1.1 Inclusions**

##### **1.1.1**

##### **1.1.2**

#### **1.2 Exclusions**

##### **1.2.1**

##### **1.2.2**

##### **1.2.3**

“sterile.”

or regional requirements for designating medical devices as “sterile.” See, for

1.2.4

1.2.5

2 Normative references

Measurement management systems — Requirements for measurement processes and

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

Sterilization of health care products — Biological indicators — Part 3: Biological indicators for

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

Sterilization of health care products — Chemical indicators — Part 3: Class 2 indicator systems

Sterilization of health care products — Chemical indicators — Part 4: Class 2 indicators as an

health care products — Chemical indicators — Part 5: Class 2 indicators for

Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile

Packaging for terminally sterilized medical devices — Part 2: Validation requirements for

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

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

Medical devices — Quality management systems — Requirements for regulatory purposes

Sterilization of medical devices — Information to be provided by the manufacturer for the

### **3 Terms and definitions**

**3.1**  
**air detector**

**3.2**  
**automatic controller**  
)

**3.3**  
**bioburden**

**3.4**  
**biological indicator**

**3.5**  
**calibration**

**3.6**  
**chemical indicator**  
**non-biological indicator**

**3.7**  
**contained product**

**3.8**  
**correction**

**3.9**  
**corrective action**

**3.10**  
**D value**  
**value**

**3.11**  
**development**

**3.12**  
**environmental control**

**3.13**  
**equilibration time**

**3.14**  
**establish**

**3.15**  
**exposure time**

**3.16**  
**fault**

3.17  
value

3.18  
health care product(s)

3.19  
holding time

3.20  
installation qualification  
IQ

3.21  
load configuration

3.22  
maintenance

3.23  
medical device

—  
—  
—  
—  
—  
—  
—  
—

**3.24**  
**measuring chain**

**3.25**  
**microorganism**

**3.26**  
**moist heat**

**3.27**  
**non-condensable gas**

**3.28**  
**operational qualification**  
**OQ**

**3.29**  
**operating cycle**

**3.30**  
**packaging system**

**3.31**  
**performance qualification**  
**PQ**



**3.32**  
**preventive action**

**3.33**  
**plateau period**

**3.34**  
**process challenge device**  
**PCD**

**3.35**  
**process parameter**

**3.36**  
**process variable**

**3.37**  
**product**

**3.38**  
**product family**  
)

**3.39**  
**reference challenge device**

**3.40**  
**reference load**

**3.41**  
**reference measuring point**

**3.42**  
**reference microorganism**

**3.43**  
**requalification**

**3.44**  
**saturated steam**

**3.45**  
**services**

**3.46**  
**specification**

**3.47**  
**specify**

**3.48**  
**sterile**

**3.49**  
**sterility**

**s**

**3.50**  
**sterility assurance level**  
**SAL**

**3.51**  
**sterilization**

**s**

**3.52**  
**sterilization load**

**3.53**  
**sterilization process**

**3.54**  
**sterilization temperature**

**3.55**  
**sterilization temperature band**

**3.56**  
**sterilizer chamber**

**3.57**  
**sterilizing agent**

**3.58**  
**thermal energy**

**3.59**  
**test of sterility**

**3.60**  
**validation**

**3.61**  
**z value**

## **4 Quality management system elements**

### **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 non-conforming product**

## **5 Sterilizing agent characterization**

### **5.1 Sterilizing agent**

#### **5.1.1**

#### **5.1.2**

### **5.2 Microbicidal effectiveness**

### **5.3 Materials effects**

### **5.4 Environmental consideration**

## **6 Process and equipment characterization**

### **6.1 Process**

#### **6.1.1 General**

**6.1.2 Saturated steam processes**

**6.1.3 Contained product processes**

## **6.2 Equipment**

### **6.2.1**

### **6.2.2**

6.2.3

6.2.4

6.2.5

6.2.6

7 Product definition

7.1

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7.5



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## 8 Process definition

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8

b) be determined by an ‘overkill’ method (see Annex D) or

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## **9 Validation**

### **9.1 General**

9.1.1

9.1.2

9.1.3

9.1.4

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9.1.5

9.1.6

9.1.7

9.1.8

### **9.2 Installation qualification (IQ)**

#### **9.2.1 Equipment**

#### **9.2.2 Installation**

#### **9.2.3 Function**

9.3 Operational qualification (OQ)

9.3.1

9.3.2

9.4 Performance qualification (PQ)

9.4.1

9.4.2

9.4.3

9.4.4

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#### 9.4.5

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—

— an “overkill” process.

#### 9.4.6

### 9

## 9.5 Review and approval of validation

### 9.5.1

### 9.5.2

10 Routine monitoring and control

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## 11 Product release from sterilization

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## 12 Maintaining process effectiveness

### 12.1 Demonstration of continued effectiveness

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## 12.2 Recalibration

### 12.3 Maintenance of equipment

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2  
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12.4 Requalification

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12.5 Assessment of change



## **Annex A**

### **Guidance**

#### **A.1 Scope**

##### **A.1.1 Inclusions**

##### **A.1.2 Exclusions**

###### **A.1.2.1**

###### **A.1.2.2**

###### **A.1.2.3**

###### **A.1.2.4**

###### **A.1.2.5**

#### **A.2 Normative references**

#### **A.3 Terms and definitions**

## **A.4 Quality management system elements**

### **A.4.1 Documentation**

### **A.4.2 Management responsibility**

### **A.4.3 Product realization**

#### **A.4.3.1**

#### **A.4.3.2**

#### **A.4.3.3**

### **A.4.4 Measurement, analysis and improvement — Control of nonconforming product**

## **A.5 Sterilizing agent characterization**

**A.6 Process and equipment characterization**

**A.7 Product definition**

**A.8 Process definition**

**A.9 Validation**

**A.10 Routine monitoring and control**

**A.11 Product release from sterilization**

A.12 Maintaining process effectiveness

Table A.1 — Elements of sterilizing agent characterization and sterilization process development, validation and routine control

Elements	Purpose	Components	Responsible party

## Annex B

### Process definition based on inactivation of the microbial population in its natural state (bioburden-based method)

#### B.1 General

#### B.2 Sampling

#### B.3 Procedure

B

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B

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B

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B

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B.3.5

#### B.4 Follow up

Annex C

Process definition based on the inactivation of a reference microorganism and a knowledge of bioburden on product items to be sterilized (combined bioburden/biological indicator based method)

C.1 General

C.2 Procedure

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C  
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C.2.5

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Annex D

Conservative process definition based on inactivation of reference microorganisms (overkill method)

D.1 General

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treatment, which is often referred to as “overkill”, can be determined either mathematically based on an

D  
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D.2 Procedure

D.2.1  
  
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D.3 Partial cycle approach

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D.4 Full cycle approach

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D



## **Annex E**

### **Operating cycles**

#### **E.1 Saturated steam — Vented systems**

**E.1.1**

**E.1.2**

**E.1.3**

#### **E.2 Saturated steam — Forced air removal**

**E.2.1**

**E.2.2**

**E.2.3**

**E.3 Air pressurization operating cycles**

**E.3.1 General**

**E.3.2 Air steam mixtures**

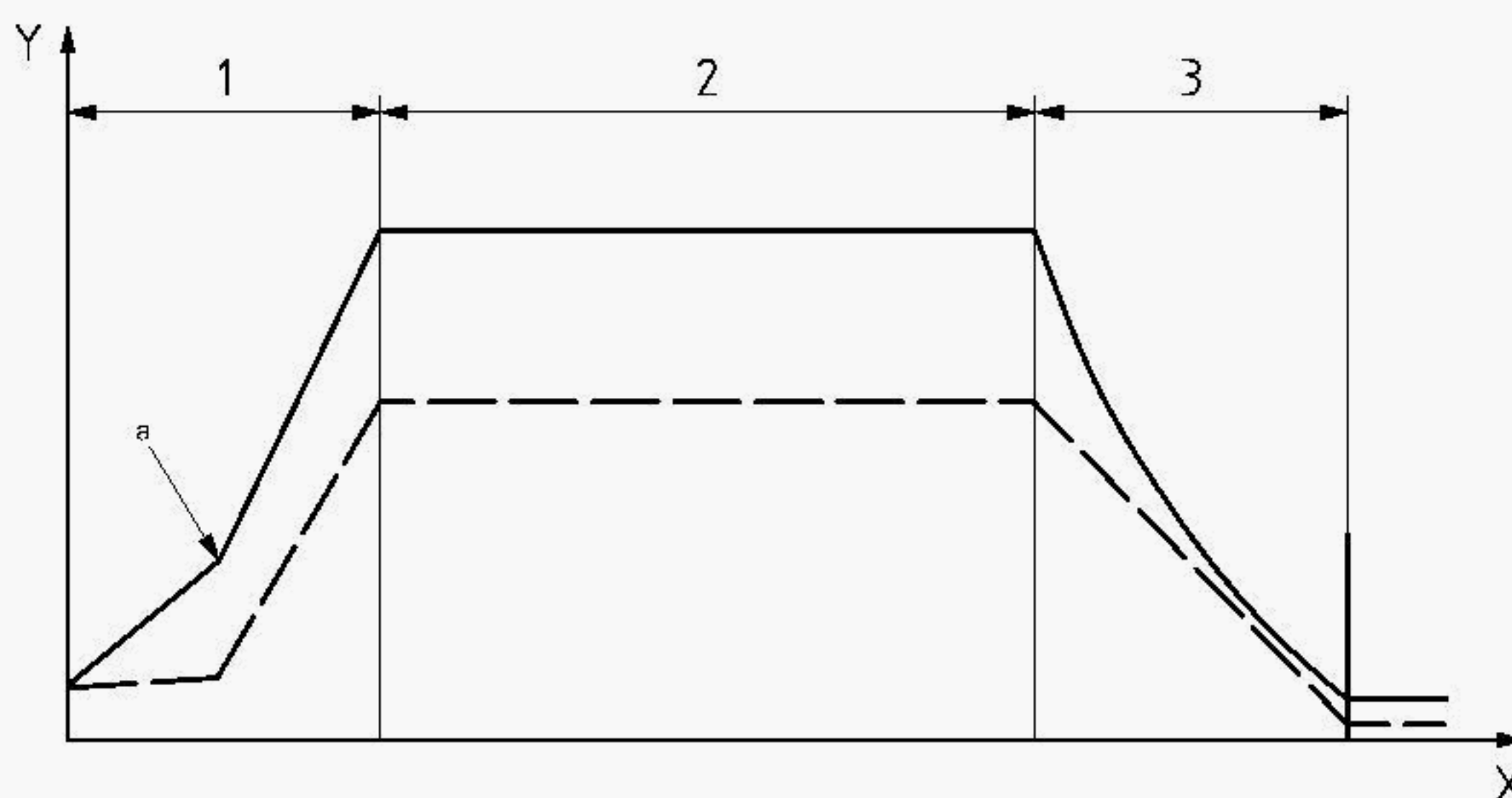
**E.3.2.1**

**E.3.2.2**

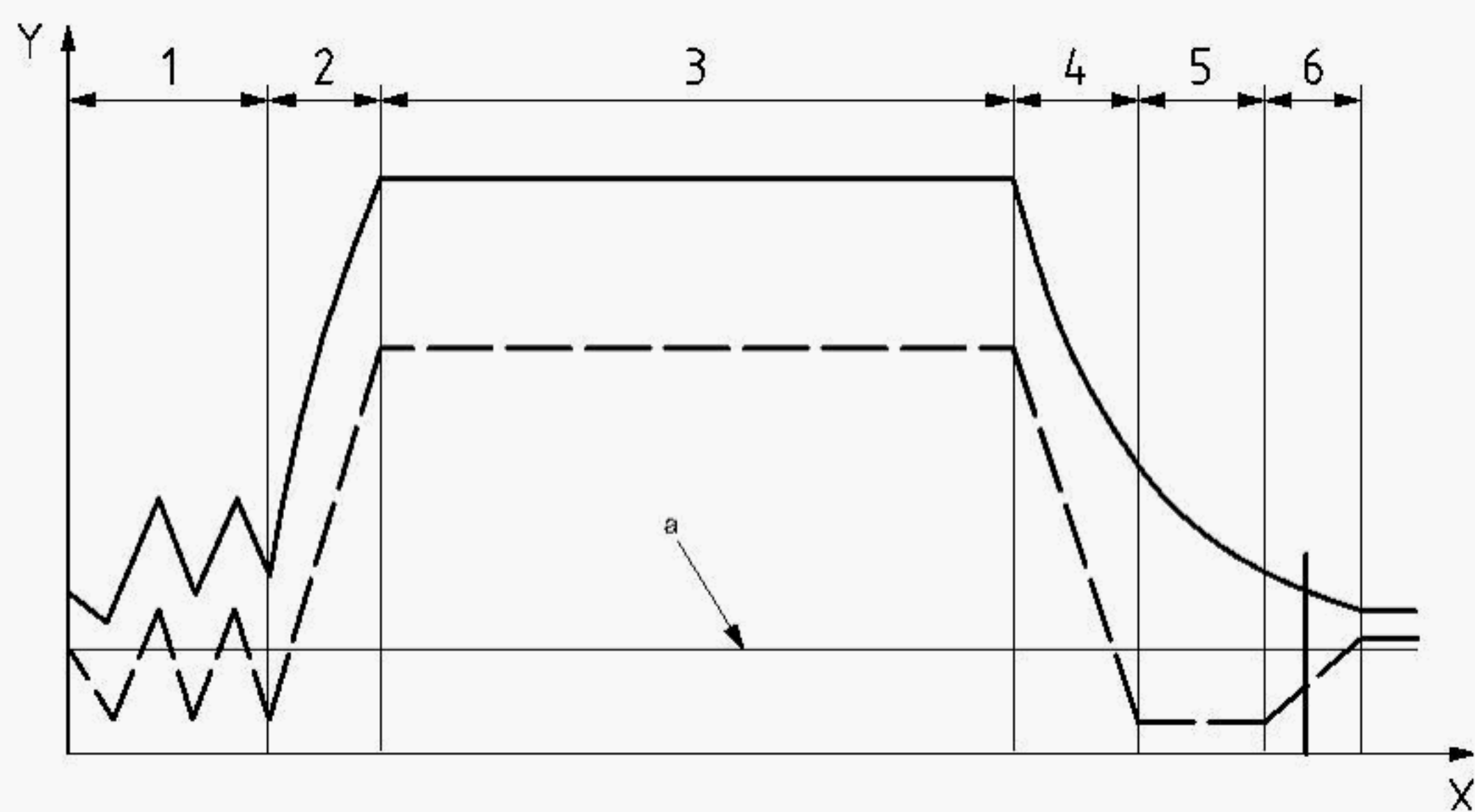
**E.3.3 Water spray**

**E.3.3.1**

**E.3.3.2**

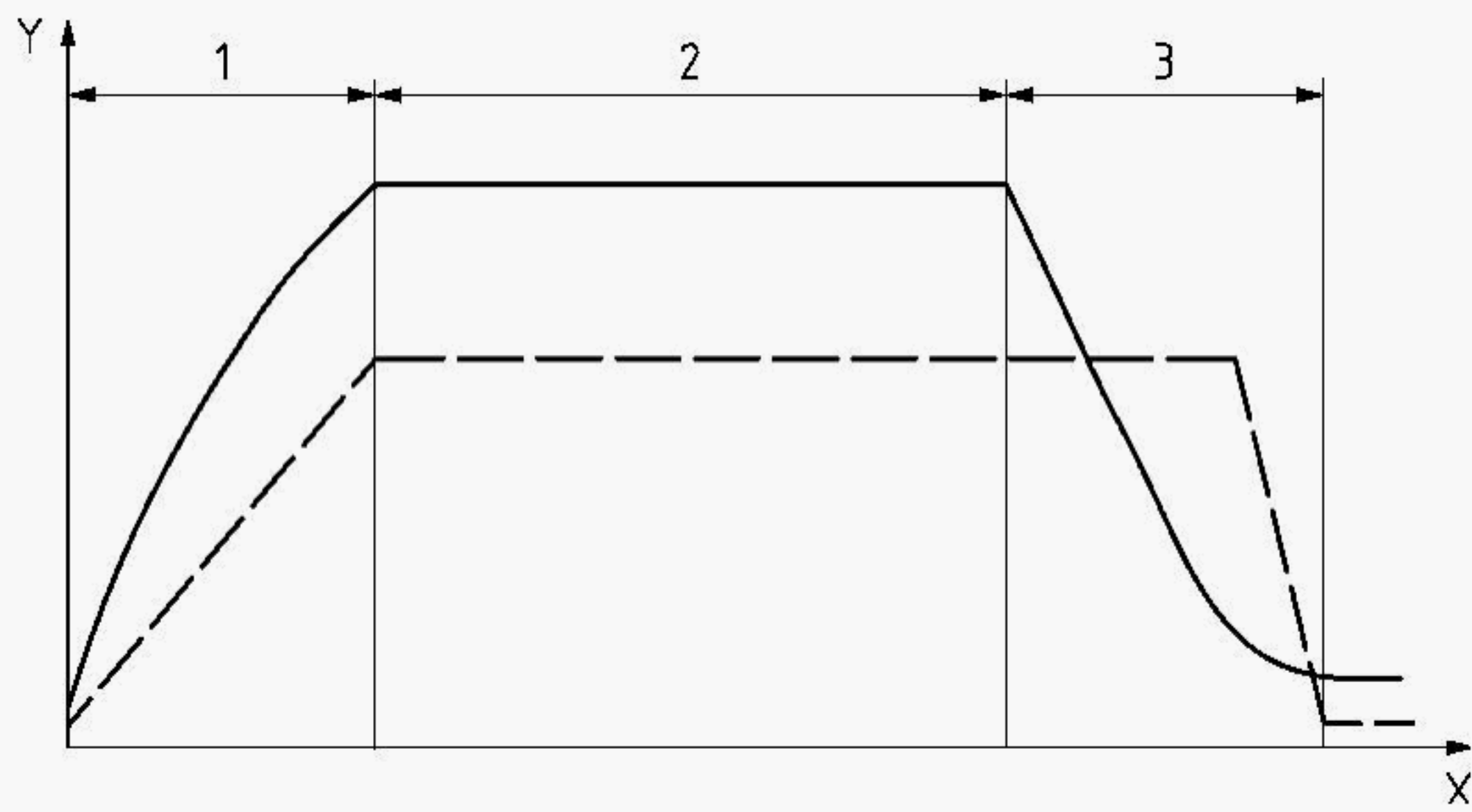
**E.3.4 Water immersion****E.3.4.1****E.3.4.2****Key**

**Figure E.1 — Example of a chamber temperature and pressure profile  
for a saturated steam vented cycle**



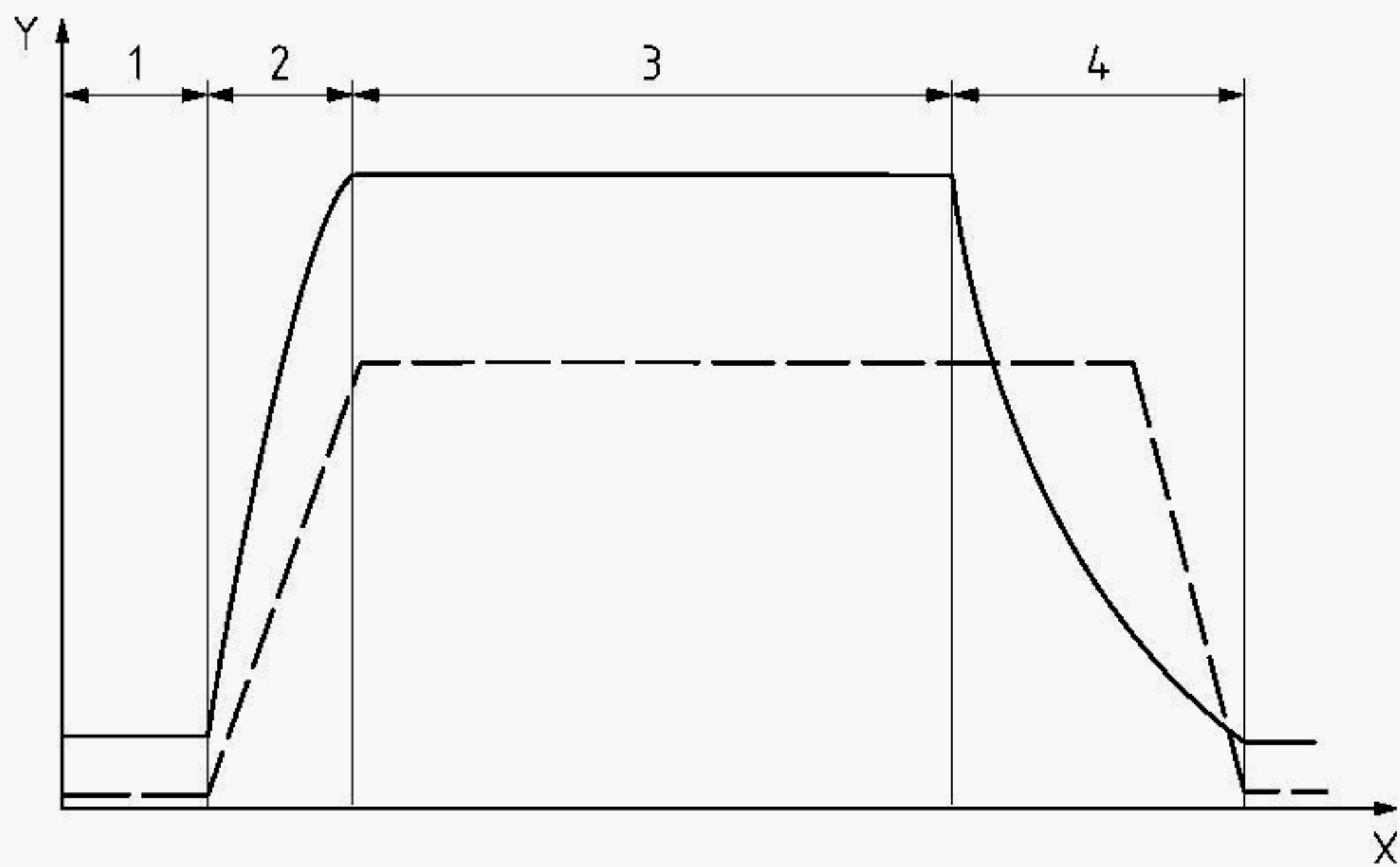
Key

Figure E.2 — Example of a chamber temperature and pressure profile for a saturated steam-forced air removal cycle



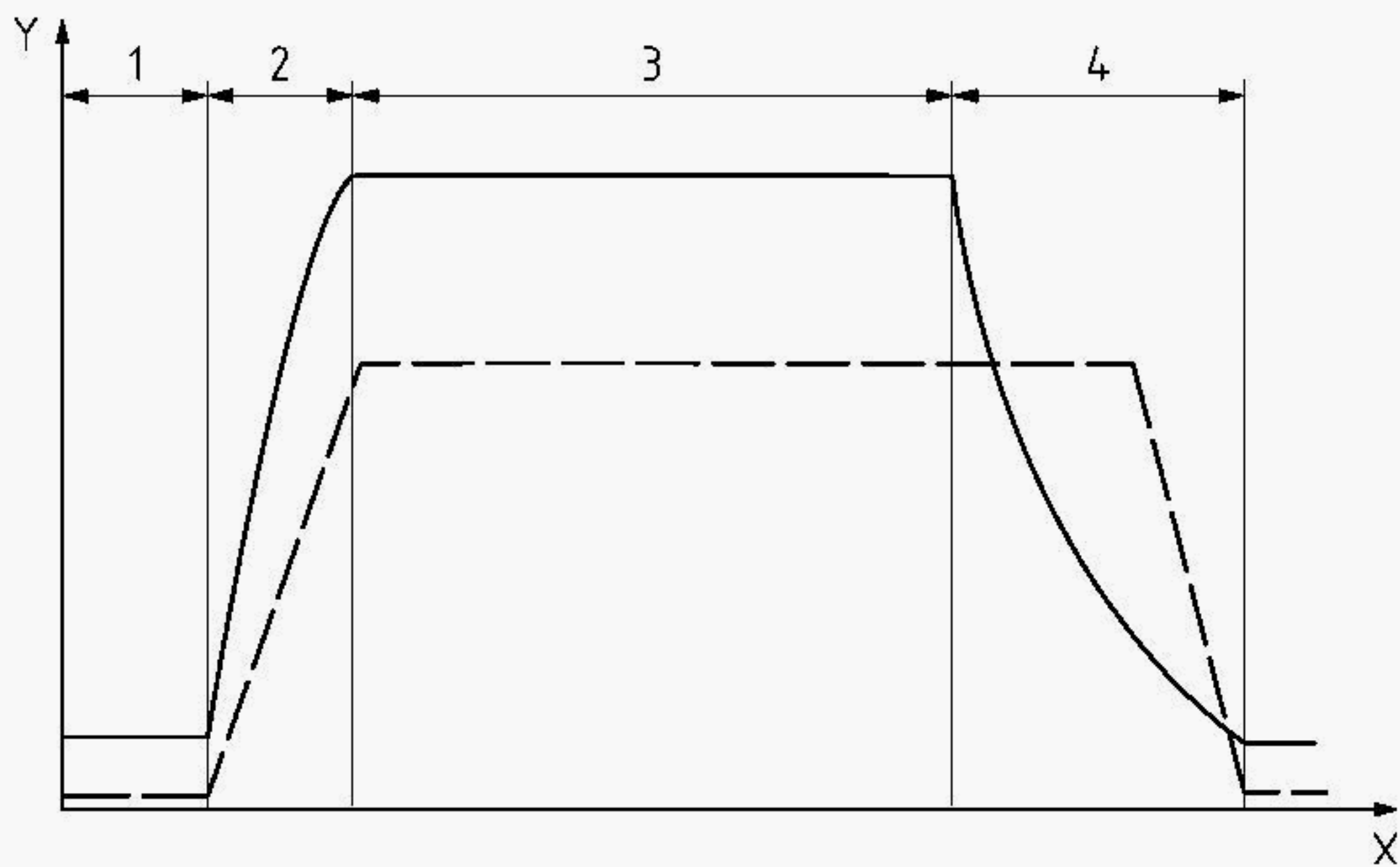
Key

Figure E.3 — Example of a chamber temperature and pressure profile for an air-steam mixture cycle



Key

Figure E.4 — Example of a chamber temperature and pressure profile for a water spray cycle



Key

Figure E.5 — Example of a chamber temperature and pressure profile for a water immersion cycle

## Bibliography

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Quality management and quality assurance standards — Part 3 Guidelines for the

Q

Quality management systems — Guidelines for performance improvements

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

Biological evaluation of medical devices — Part 17: Establishment of allowable limits

Sterilization of healthcare products — Vocabulary

Environmental management systems — Requirements with guidance for use

— Life cycle assessment — Principles and framework

Sterilization of health care products — Biological indicators — Guidance for the

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

s — Application of risk management to medical devices

Sterilization of health care products — Chemical indicators — Guidance for selection,

Washer-disinfectors — Part 1: General requirements, terms, definitions and tests

Washer-disinfectors — Part 2: Requirements and tests for washer disinfectors

Washer-disinfectors — Part 4: Requirements and tests for washer-disinfectors

Sterilization of health care products — Requirements for products labeled  
“STERILE”

Sterilization — Steam sterilizers — Large sterilizers

Sterilization of medical devices — Requirements for medical devices to be designated “STERILE” — Part 1: Requirements for terminally-sterilized medical devices

Packaging materials and systems for medical devices which are to be sterilized —

Packaging materials and systems for medical devices which are to be sterilized —  
wrap — Requirements and test methods

Packaging materials and systems for medical devices which are to be sterilized —

reels (specified in EN 868-5) — Requirements and test methods

Packaging materials and systems for medical devices which are to be sterilized —  
Part 4: Paper bags — Requirements and test methods

Packaging materials and systems for medical devices which are to be sterilized —  
Part 5: Heat and self-sealable pouches and reels of paper and plastic film construction —

Packaging materials and systems for medical devices which are to be sterilized —  
Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 — Requirements

Packaging materials and systems for medical devices which are to be sterilized —

pouches, reels and lids — Requirements and test methods

Packaging materials and systems for medical devices which are to be sterilized —

s

devices — Part 1: Analysis and management of risk

devices — Part 2: Controls on sourcing, collection and handling

devices — Part 3: Validation of the elimination and/or inactivation of viruses and transmissible agents

Global Harmonization Task Force (GHTF) — Study Group 1 (SG1), Document N029R15, dated

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a

Sterilization of health care products — Biological and chemical indicators — Test

Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk

utilizing animal tissues and their derivatives — Part 2: Controls on

Medical devices utilizing animal tissues and their derivatives — Part 3: Validation of the



ANNEX ZA

Relationship between this European Standard and the Essential Requirements of EU Directives 90/385/EEC, 93/42/EEC and 98/79/EEC

Table ZA.1 – Correspondence between this European Standard and Directives 90/385/EEC, 93/42/EEC and 98/79/EC

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