

English Version

**Packaging for terminally sterilized medical devices - Part 2:
Validation requirements for forming, sealing and assembly
processes (ISO 11607-2:2006)**

Emballages des dispositifs médicaux stérilisés au stade terminal - Partie 2: Exigences de validation pour les procédés de formage, scellage et assemblage (ISO 11607-2:2006)

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 2: Validierungsanforderungen an Prozesse der Formgebung, Siegelung und des Zusammenstellens (ISO 11607-2:2006)

This European Standard was approved by CEN on 13 April 2006.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



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

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

Foreword

Endorsement notice

ANNEX ZA

Relationship between this International Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

Table ZA.1 — Correspondence between this International Standard and Directive 93/42/EEC on medical devices

Clause(s)/Sub-clause(s) of this International Standard	Essential Requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes

W

**Packaging for terminally sterilized
medical devices —**

**Validation requirements for forming,
sealing and assembly processes**

Emballages des dispositifs médicaux stérilisés au stade terminal —

PDF disclaimer

Contents

Foreword.....	iv
Introduction.....	v
1 Scope	1
2 Normative references	1
3 Terms and definitions.....	1
4 General requirements.....	4
4.1 Quality systems	4
4.2 Sampling.....	4
4.3 Test methods.....	4
4.4 Documentation.....	5
5 Validation of packaging processes.....	5
5.1 General.....	5
5.2 Installation qualification (IQ)	6
5.3 Operational qualification (OQ).....	6
5.4 Performance qualification (PQ).....	7
5.5 Formal approval of the process validation	8
5.6 Process control and monitoring	8
5.7 Process changes and revalidation.....	8
6 Packaging system assembly.....	8
7 Use of reusable sterile barrier systems.....	9
8 Sterile fluid-path packaging.....	9
A	
Bibliography.....	11

Foreword

—

—

Introduction

One significant barrier to harmonization was terminology. The terms “package”, “final package”, “final pack”, “primary pack”, and “primary package” all have different connotations around the globe and choosing one of completion of this document. As a result, the term “sterile barrier system” was introduced to describe the sterilization, to provide an acceptable microbial barrier, and to allow for aseptic presentation. “Protective packaging” protects the sterile barrier system, and together they form the packaging system. “Preformed sterile barrier systems” would include any partially assembled sterile barrier systems such as pouches, header

Packaging for terminally sterilized medical devices —

Validation requirements for forming, sealing and assembly processes

1 Scope

2 Normative references

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

3 Terms and definitions

3.1
expiry date

3.2
installation qualification
IQ

**3.3
labelling**

**3.4
operational qualification
OQ**

**3.5
packaging system**

**3.6
performance qualification
PQ**

**3.7
preformed sterile barrier system**

**3.8
process development**

**3.9
product**

**3.10
protective packaging**

3.15
sterile fluid-path packaging

3.16
validation

4 General requirements

4.1 Quality systems

4.1.1

4.1.2

4.1.3

4.2 Sampling

4.3 Test methods

4.3.1

4.3.2

—

—

—

—

—

4.3.3

4.4 Documentation

4.4.1

4.4.2

4.4.3

4.4.4

5 Validation of packaging processes

5.1 General

5.1.1

—

—

—

—

—

—

—

—

5

.

5.1.3

5.1.4

5.1.5

5.2 Installation qualification (IQ)

5.2.1

—

—

—

—

—

—

—

—

—

—

5.2.2

5.2.3

5.2.4

5.2.5

5.2.6

5.2.7

5.3 Operational qualification (OQ)

5.3.1

5.3.2

—

-
-
-
-
-
-
-
-
-
-

5.4 Performance qualification (PQ)

5.4.1

5.4.2

-
-
-
-
-

5.4.3

5.4.4

5.4.5

5.4.6

5.4.7

5.5 Formal approval of the process validation

5.5.1

5.5.2

5.6 Process control and monitoring

5.6.1

5.6.2

5.7 Process changes and revalidation

5.7.1

5.7.2

—

—

—

—

—

5.7.3

5.7.4

6 Packaging system assembly

6.1

6.2

6.3

7 Use of reusable sterile barrier systems

8 Sterile fluid-path packaging

8

8.2 Medical devices labelled “sterile fluid path” shall maintain sterility of the fluid path by the construction of

Annex A

Process development

—
—
—
—
—

—
—
—
—
—

Bibliography

Paper and board — Sampling to determine average quality

Sampling procedures for inspection by attributes — Part 1: Sampling schemes

Quality management systems — Requirements

Sterilization of health care products — Vocabulary

Medical devices — Quality management systems – Requirements for regulatory

Quality management systems — Fundamentals and vocabulary

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 —

irradiation — Requirements and test methods

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

clinical staff and equipment — Part 1: General requirements for manufacturers, processors and

Sterilization — Sterile supply — Part 7: Use of sterilization paper, nonwoven

Sterilization — Sterile supply — Part 8: Logistics of sterile medical devices

Sterilization — Sterile supply — Part 9: Handling of sterilization containers

Egne notater/Notes: