

IRISH STANDARD

I.S. EN 12297:1998

ICS 07.080 07.100.01

National Standards Authority of Ireland Dublin 9 Ireland

Tel: (01) 807 3800 Tel: (01) 807 3838

BIOTECHNOLOGY - EQUIPMENT GUIDANCE ON TESTING PROCEDURES
FOR STERILIZABILITY

This Irish Standard was published under the authority of the National Standards Authority of Ireland and comes into effect on: July 17, 1998

NO COPYING WITHOUT NSAI PERMISSION EXCEPT AS PERMITTED BY COPYRIGHT LAW

© NSAI 1998

Price Code G

Údarás um Chaighdeáin Náisiúnta na hÉireann

This is a free page sample. Access the full version online.

DECLARATION

OF

SPECIFICATION

ENTITLED

BIOTECHNOLOGY - EQUIPMENT - GUIDANCE ON TESTING PROCEDURES FOR STERILIZABILITY

AS

THE IRISH STANDARD SPECIFICATION FOR

BIOTECHNOLOGY - EQUIPMENT - GUIDANCE ON TESTING PROCEDURES FOR STERILIZABILITY

NSAI in exercise of the power conferred by section 16 (3) of the National Standards Authority of Ireland Act, 1966 (No. 28 of 1996) and with the consent of the Minister for Enterprise, Trade and Employment, hereby declares as follows:

- 1. This instrument may be cited as the Standard Specification (Biotechnology Equipment Guidance on testing procedures for sterilizability) Declaration, 1998.
- 2. (1) The Specification set forth in the schedule to this declaration is hereby declared to be the standard specification for Biotechnology Equipment Guidance on testing procedures for sterilizability. The Schedule comprises the text of EN 12297:1998.
- (2) The said standard specification may be cited as Irish Standard EN 12297:1998 or as I.S. EN 12297:1998.

This is a free page sample. Access the full version online.

EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

EN 12297

March 1998

ICS

Descriptors:

biotechnology, medical equipment, sterilization, disinfection, contamination, micro-organisms, noxious micro-organisms, tests, safety, hygiene conditions, inspection, accident prevention, environmental protection, work safety

English version

Biotechnology - Equipment - Guidance on testing procedures for sterilizability

Biotechnologie - Equipement - Guide des procédures d'essai pour le contrôle de la capacité à la stérilisation

Biotechnik - Geräte und Ausrüstungen - Leitfaden für Verfahren zur Prüfung der Sterilisierbarkeit

This European Standard was approved by CEN on 2 March 1998.

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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION COMITÉ EUROPÉEN DE NORMALISATION EUROPAISCHES KOMITEE FUR NORMUNG

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Page 2 EN 12297:1998

Contents

| Fo | reword | 3 |
|----|--|----|
| 1 | Scope | 3 |
| 2 | Definitions | 3 |
| 3 | Testing | 5 |
| 4 | Documentation | 7 |
| An | nex A (informative) Guidance on selection of sterilizability testing | 8 |
| An | nex B (informative) Information on test methods for sterilizability | 12 |
| An | nex C (informative) Bibliography | 15 |



| | This is a free preview. | Purchase the e | entire publication | at the link below: |
|--|-------------------------|----------------|--------------------|--------------------|
|--|-------------------------|----------------|--------------------|--------------------|

Product Page

- Dooking for additional Standards? Visit Intertek Inform Infostore
- Dearn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation