



National Standards Authority of Ireland

IRISH STANDARD

I.S. EN 1619:1997

ICS 07.080

**BIOTECHNOLOGY - LARGE-SCALE
PROCESS AND PRODUCTION - GENERAL
REQUIREMENTS FOR MANAGEMENT AND
ORGANIZATION FOR STRAIN
CONSERVATION PROCEDURES**

National Standards
Authority of Ireland
Dublin 9
Ireland

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

*This Irish Standard was
published under the
authority of the National
Standards Authority of
Ireland
and comes into effect on.
April 25, 1997*

**NO COPYING WITHOUT NSAI
PERMISSION EXCEPT AS
PERMITTED BY COPYRIGHT
LAW**

© NSAI 1997

Price Code F

Údarás um Chaighdeáin Náisiúnta na hÉireann

DECLARATION

OF

SPECIFICATION

ENTITLED

BIOTECHNOLOGY - LARGE-SCALE PROCESS AND PRODUCTION - GENERAL

REQUIREMENTS FOR MANAGEMENT AND ORGANIZATION FOR STRAIN

CONSERVATION PROCEDURES

AS

THE IRISH STANDARD SPECIFICATION FOR

BIOTECHNOLOGY - LARGE-SCALE PROCESS AND PRODUCTION - GENERAL

REQUIREMENTS FOR MANAGEMENT AND ORGANIZATION FOR STRAIN

CONSERVATION PROCEDURES

Forfás in exercise of the power conferred by section 20 (3) of the Industrial Research and Standards Act, 1961 (No. 20 of 1961) and the Industrial Development Act, 1993 (No. 19 of 1993), and with the consent of the Minister for Enterprise and Employment, hereby declares as follows:

1. This instrument may be cited as the Standard Specification (Biotechnology - Large-scale process and production - General requirements for management and organization for strain conservation procedures) Declaration, 1997.
2. (1) The Specification set forth in the Schedule to this declaration is hereby declared to be the standard specification for Biotechnology - Large-scale process and production - General requirements for management and organization for strain conservation procedures. The Schedule comprises the text of EN 1619:1996.

(2) The said standard specification may be cited as Irish Standard/EN 1619 :1997 or as I.S./EN 1619:1997.

EUROPEAN STANDARD

EN 1619

NORME EUROPÉENNE

EUROPÄISCHE NORM

July 1996

ICS 07.100.00

Descriptors: biotechnology, reproduction (biology), culture (biology), micro-organisms, designation, preservation, hazards, management, organization, storage

English version

**Biotechnology - Large-scale process and
production - General requirements for
management and organization for strain
conservation procedures**

Biotechnologie - Procédé à grande échelle et
production - Exigences générales de gestion et
d'organisation pour les procédures de
conservation des souches

Biotechnik - Verfahren im Großmaßstab und
Produktion - Allgemeine Anforderungen für
Verwaltung und Organisation bei Verfahren zur
Stammkonservierung

This European Standard was approved by CEN on 1996-05-02. 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.

The European Standards exist 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, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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

Contents

Introduction	4
1 Scope	4
2 Normative references	4
3 Definitions	4
4 Development of master and working cell banks	6
5 Classification of microorganisms	6
6 Preservation	6
7 Characterization	7
8 Handling and storage	7
9 Personnel and facilities	8
Annex A (informative) Classification of the microorganisms	9
Annex B (informative) Bibliography	11

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

[Product Page](#)

-
- [Looking for additional Standards? Visit Intertek Inform Infostore](#)
 - [Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation](#)
-