

IRISH STANDARD

I.S. EN 12307:1998

ICS 07.080 07.100.99

National Standards Authority of Ireland Dublin 9 Ireland

Tel. (01) 807 3800 Tel (01) 807 3838

BIOTECHNOLOGY - LARGE-SCALE
PROCESS AND PRODUCTION - GUIDANCE
FOR GOOD PRACTICE, PROCEDURES,
TRAINING AND CONTROL FOR PERSONNEL

This Irish Standard was published under the authority of the National Standards Authority of Ireland and comes into effect on: May 15, 1998

NO COPYING WITHOUT NSAI PERMISSION EXCEPT AS PERMITTED BY COPYRIGHT LAW

© NSAI 1998

Price Code F

Údarás um Chaighdeáin Náisiúnta na hÉireann

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

#### **DECLARATION**

OF

#### **SPECIFICATION**

#### **ENTITLED**

BIOTECHNOLOGY - LARGE-SCALE PROCESS AND PRODUCTION - GUIDANCE FOR GOOD PRACTICE, PROCEDURES, TRAINING AND CONTROL FOR PERSONNEL

AS

#### THE IRISH STANDARD SPECIFICATION FOR

BIOTECHNOLOGY - LARGE-SCALE PROCESS AND PRODUCTION - GUIDANCE FOR GOOD PRACTICE, PROCEDURES, TRAINING AND CONTROL FOR PERSONNEL

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 Large-scale process and production Guidance for good practice, procedures, training and control for personnel) Declaration, 1998.
- 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 Guidance for good practice, procedures, training and control for personnel. The Schedule comprises the text of EN 12307:1997.
- (2) The said standard specification may be cited as Irish Standard EN 12307:1998 or as I.S. EN 12307:1998.

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

# **EUROPEAN STANDARD** NORME EUROPÉENNE **EUROPÄISCHE NORM**

EN 12307

October 1997

ICS 07.080; 07.100.99

Descriptors: biotechnology, good laboratory practices, work safety, accident prevention, environmental protection, hazards, contamination, micro-organisms, noxious micro-organisms, classifications, personnel, training, specifications

English version

## Biotechnology - Large-scale process and production - Guidance for good practice, procedures, training and control for personnel

Biotechnologie - Procédé à grande échelle et production -Guide de bonnes pratiques, procédures, formation et contrôle pour le personnel

Biotechnik - Verfahren im Großmaßstab und Produktion -Leitfaden für gute Praxis, Arbeitsabläufe, Ausbildung und Überwachung des Personals

This European Standard was approved by CEN on 21 August 1997.

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 EUROPÄISCHES KOMITEE FUR NORMUNG

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

### Contents

Fore	word	. 3
Intro	duction	. 4
1	Scope	. 4
2	Normative references	•••
3	Definitions	. 5
4	General considerations	. 6
5	Recommendations for handling microorganisms in large scale process and production activities	. 6
6	Instructions and training	. 9
Anne	x A (informative) Bibliography	11



	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