



National Standards Authority of Ireland

IRISH STANDARD

**I.S. EN 12307:1998**

ICS 07.080  
07.100.99

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

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Údarás um Chaighdeáin Náisiúnta na hÉireann



## **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**

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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.



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.

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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.

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COMITÉ EUROPÉEN DE NORMALISATION  
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