National Standards Authority of Ireland

IRISH STANDARD

**I.S. EN 13312-2:2001**

ICS 07.080
07.100.01

# BIOTECHNOLOGY - PERFORMANCE CRITERIA FOR PIPING AND INSTRUMENTATION - PART 2: COUPLINGS

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*This Irish **Standard** was published under the authority of the National **Standards** Authority of Ireland and comes into effect on: August 11, 2001*



**Price Code F**

Údarás um Chaighdeáin Náisiúnta na hÉireann

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN 13312-2

February 2001

ICS 07.080; 07.100.01

English version

# Biotechnology - Performance criteria for piping and instrumentation - Part 2: Couplings

Biotechnologie - Critères de performance pour tuyauteries et instrumentation - Partie 2: Raccords

Biotechnik - Leistungskriterien fur Leitungssysteme und Instrumentierung - Teil 2: Verbindungsstücke

This European Standard was approved by CEN on 13 January 2001.

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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 Management Centre 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 EUROPEEN DE NORMALISATION
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Ref. No. EN 13312-2:2001 E

## Contents

## Foreword

This European Standard has been prepared by Technical Committee CEN/TC 233 "Biotechnology", the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2001, and conflicting national standards shall be withdrawn at the latest by August 2001.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

This standard is one of a series of European Standards concerned with performance criteria for piping and instrumentation. These standards are :

EN 13312-1, *Biotechnology - Performance criteria for piping and instrumentation - Part 1 : General performance criteria.*

EN 13312-2, *Biotechnology - Performance criteria for piping and instrumentation - Part 2 : Couplings.*

EN 13312-3, *Biotechnology - Performance criteria for piping and instrumentation - Part 3 : Sampling and inoculation devices.*

EN 13312-4, *Biotechnology - Performance criteria for piping and instrumentation - Part 4 : Tubes and pipes.*

EN 13312-5, *Biotechnology - Performance criteria for piping and instrumentation - Part 5 : Valves.*

EN 13312-6, *Biotechnology - Performance criteria for piping and instrumentation - Part 6 : Equipment probes.*

This standard includes a Bibliography.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

## Introduction

Couplings are used for joining tubular sections, and for connecting other components of equipment into the process system, where equipment is designed to be disassembled. In many cases couplings are made of stainless steel and are used in all food, beverage, pharmaceutical and biotechnological processes.

Detailed design specifications are necessary to ensure interchangeability and connectability, since frequently the various parts of a coupling will be manufactured by different organisations. As an example, control and measuring devices are often supplied with couplings on the connecting ports which have to be secured to tube systems with mating parts and gaskets supplied by third parties.

Couplings are designed to be leakproof under normal operating conditions. In biotechnological applications they should in relevant cases prevent the release of microorganisms into the atmosphere and ingress into the process system. Couplings should enable process equipment to be cleaned in place or dismantled for manual cleaning and/or sterilization in an autoclave. Typical coupling standards are given in bibliography [3] to [10].

In relevant cases couplings themselves should be capable of being cleaned and/or sterilized in place.

The continuously reliable performance of a coupling is dependent on features and conditions which are not integral parts of this European Standard, and therefore attention is drawn to the recommendations for design, installation and maintenance in annex B.

Use of this European Standard will aid the equipment manufacturer in the classification of couplings with regard to safe performance in biotechnological processes. The classification is easily understandable and readily utilizable for the user and the regulatory authorities.

## 1 Scope

This European Standard specifies performance criteria for couplings used in biotechnological processes with respect to the potential hazards to the worker and the environment from microorganisms in use.

This European Standard applies where the intended use of the coupling includes hazardous or potentially hazardous microorganisms used in biotechnological processes or where exposure of the worker or the environment to such microorganisms is restricted for reasons of safety.

## 2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).