This preview is downloaded from www.sis.se. Buy the entire standard via https://www.sis.se/std-32636

SWEDISH STANDARDS INSTITUTE

# SVENSK STANDARD
# SS-EN 13641

Fastställd 2002-06-28

Utgåva 1

# In vitro-diagnostik – Eliminering eller reduktion av infektionsrisk relaterad till in vitro-diagnostiska medicintekniska produkter

# Elimination or reduction of risk of infection related to in vitro diagnostic reagents

ICS 11.100

Språk: engelska

Tryckt i augusti 2002

© Copyright SIS. Reproduction in any form without permission is prohibited.

This preview is downloaded from www.sis.se. Buy the entire standard via https://www.sis.se/std-32636

Europastandarden EN 13641:2002 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN 13641:2002.

The European Standard EN 13641:2002 has the status of a Swedish Standard. This document contains the official English version of EN 13641:2002.

Dokumentet består av 10 sidor.

Upplysningar om **sakinnehållet** i standarden lämnas av SIS, Swedish Standards Institute, tel 08 - 555 520 00.

Standarder kan beställas hos SIS Förlag AB som även lämnar **allmänna upplysningar** om svensk och utländsk standard.
*Postadress*: SIS Förlag AB, 118 80 STOCKHOLM
*Telefon*: 08 - 555 523 10. *Telefax*: 08 - 555 523 11
*E-post*: sis.sales@sis.se. *Internet*: www.sisforlag.se

This preview is downloaded from www.sis.se. Buy the entire standard via https://www.sis.se/std-32636

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN 13641

May 2002

ICS 11.100

English version

# Elimination or reduction of risk of infection related to in vitro diagnostic reagents

Elimination ou réduction du risque d'infection relatif aux réactifs de diagnostic in vitro

Eliminierung oder Herabsetzung des von Reagenzien für in-vitro-diagnostische Untersuchungen ausgehenden Infektionsrisikos

This European Standard was approved by CEN on 5 January 2002.

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 Management Centre 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 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, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

**Management Centre: rue de Stassart, 36 B-1050 Brussels**

© 2002 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.

Ref. No. EN 13641:2002 E

This preview is downloaded from www.sis.se. Buy the entire standard via https://www.sis.se/std-32636


## Foreword

This document EN 13641:2002 has been prepared by Technical Committee CEN/TC 140 "In vitro diagnostic medical devices", the secretariat of which is held by DIN.

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 November 2002, and conflicting national standards shall be withdrawn at the latest by November 2002.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative annex ZA, which is an integral part of this document.

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, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

This preview is downloaded from www.sis.se. Buy the entire standard via https://www.sis.se/std-32636



## Introduction

Although medical laboratory staff routinely handle specimens that are potentially infectious and appropriate protective measures and safety procedures have to be followed, according to the provisions of the Directive 98/79/EC on in vitro diagnostic medical devices (IVD MDs) (see Bibliography, [1]) the additional risk of accidental infection caused by IVD MDs containing infectious or potentially infectious material is to be reduced to a minimum. This requirement of the EU Directive is an essential requirement relating to the design and manufacture of IVD MDs. Manufacturers are obliged to ensure by appropriate design features and manufacturing procedures that the risk of infection presented by the product itself is minimal. The EU Directive does not specifically address the following aspects which are covered by specific international, European and/or national legislation:

– general aspects of workers' protection and the measures that have to be implemented when infectious or potentially infectious materials are handled in laboratories or manufacturing sites,

– transportation of infectious goods,

– disposal routes and processes.

This preview is downloaded from www.sis.se. Buy the entire standard via https://www.sis.se/std-32636


# 1 Scope

This European Standard specifies requirements related to design and manufacture in order to effectively control the risk of infection caused by in vitro diagnostic reagents including reagent products, calibrators, control materials and kits, hereinafter called IVD reagents. The standard is applicable to in vitro diagnostic reagents containing material of human origin. The standard is also applicable to in vitro diagnostic reagents containing materials obtained by biotechnology processes or materials of animal origin, in particular in view of relevant zoonoses, when the results of a risk analysis reveal that there is a risk of human infection.

The standard does not apply to the following:

– instruments and specimen receptacles;

NOTE 1 The prevention of infection due to handling of biological materials throughout such equipment is addressed in other relevant International and/or European Standards.

– general aspects of workers' protection;

– transportation of infectious goods;

– disposal measures.

NOTE 2 Some of the most relevant documents relating to aspects not covered by this standard are listed in Bibliography for information.

# 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).

EN 375, *Information supplied by the manufacturer with in vitro diagnostic reagents for professional use.*

EN 376, *Information supplied by the manufacturer with in vitro diagnostic reagents for self-testing.*

# 3 Terms and definitions

For the purposes of this European Standard, the following terms and definitions apply.

**3.1**
**potentially infectious biological material**
material which might contain infectious viable transmissible agents albeit with a low probability

NOTE Potentially infectious biological material includes all human and all animal sourced materials, including the specimens for routine diagnostic examination and biological materials of unknown origin.

**3.2**
**infectious biological material**
material which is known or highly likely to contain viable microorganisms or other transmissible agents which are known or suspected to cause disease in humans

NOTE Other transmissible agents are e.g. prions.