EESTI STANDARD EVS-EN 13975:2003

Diagnostiliste in vitro meditsiiniseadmete vastuvõtul teostatava testimise osaks olevad proovivõtumeetodid. Statistilised aspektid

Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspects

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN 13975:2003 sisaldab Euroopa standardi EN 13975:2003 ingliskeelset teksti. Käesolev dokument on jõustatud 15.04.2003 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 13975:2003 consists of the English text of the European standard EN 13975:2003. This document is endorsed on 15.04.2003 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This European Standard specifies sampling procedure requirements for acceptance testing of finished in vitro diagnostic medical devices, which require EC verification by a notified body	**Scope:** This European Standard specifies sampling procedure requirements for acceptance testing of finished in vitro diagnostic medical devices, which require EC verification by a notified body

ICS 11.100

Võtmesõnad: chemical analysis and testin, dimensional measurements, instructions, medicine, quality assurance progra, sampling, sampling m, size measurement, specification (approval), specifications, statistical analysis, statistical methods of analysis, statistics, testing

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Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspects

Procédures d'échantillonnage utilisées pour l'acceptation des essais des dispositifs médicaux de diagnostic in vitro - Aspects statistiques

Probenahmeverfahren für die Annahmeprüfung von In-vitro-Diagnostika - Statistische Aspekte

This European Standard was approved by CEN on 14 November 2002.

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

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Foreword

This document (EN 13975:2003) 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 September 2003, and conflicting national standards shall be withdrawn at the latest by September 2003.

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

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

Annex A is informative.

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, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This European Standard relates to Annex VI "EC VERIFICATION" of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, setting out requirements for sampling procedures used for acceptance testing of in vitro diagnostic medical devices by a notified body.

In Annex VI three provisions for verification are described:

— Section 5 provides for verification by examination and testing of every finished device;

— Section 6.3 provides for verification based on statistical control by attributes and/or variables;

— Section 2.2 provides for alternative conformity assessment procedures for those situations where statistical verification as specified in Section 6.3 is considered to be not appropriate.

The first provision is not considered in the present standard since the associated sampling plan requires no statistical considerations.

The second provision is applied when sufficient certainty on the result of such verification on finished devices can be gained by a sampling plan established on a statistical basis. For this purpose existing standards on acceptance testing can be applied.

The third provision is addressed in Section 2.2 of Annex VI which states that:

"To the extent that for certain aspects the final testing according to Section 6.3 is not appropriate, adequate in-process testing, monitoring and control methods shall be established by the manufacturer with the approval of the notified body. The provision of Annex IV, Section 5, shall apply accordingly in relation to the above mentioned approved procedures."

Annex IV, Section 5, prescribes surveillance and approval of a manufacturer's quality system.

It is current state of the art that inspection and verification of the finished devices is complementary to process control and final testing performed by the manufacturer. Performance verification is generally performed by measurements on defined control materials or a defined panel of reference specimens (e.g. sera).

Valid conclusions can only be drawn from a limited number of units of the final product, if adequate in-process testing, monitoring and control procedures ensure the homogeneity of the final product batch and its components at the intermediate stage(s) of manufacture as well as the suitability of the process applied. Any sampling plan used for final testing of in vitro diagnostic medical devices is based on statistical considerations. This does not necessarily mean that a large number of units is sampled and tested. In many cases using very small sample sizes (sometimes equal to one unit) can be an acceptable approach, provided that an adequate level of conformity has been demonstrated by other appropriate means.

Following this last approach, this standard can also be used for establishing sampling procedures when annex III or IV or VII is applied.

1 Scope

This European Standard specifies sampling procedure requirements for acceptance testing of finished in vitro diagnostic medical devices, which require EC verification by a notified body.

Two different provisions are addressed:

a) verification by testing attributes and/or variables on a statistical basis;

b) verification by testing a homogeneous batch which has been defined by appropriate means of process validation and in-process control.

This standard specifies requirements and criteria for testing procedures to establish and verify the homogeneity of processes and products. This standard is also applicable for drawing up sampling plans for finished products according to the requirements laid down for manufacturers' product certification and production quality systems.

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).

ISO 2859-1, *Sampling procedures for inspection by attributes — Part 1: Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection.*

ISO 2859-2, *Sampling procedures for inspection by attributes — Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection.*

ISO 2859-3, *Sampling procedures for inspection by attributes — Part 3: Skip-lot sampling procedures.*

ISO 3951, *Sampling procedures and charts for inspection by variables for percent nonconforming.*

3 Terms and definitions

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

3.1
acceptable quality level
AQL
quality level that for the purpose of sampling inspection of a continuous series of batches is the limit of a satisfactory process average

3.2
acceptance testing
sampling inspection
process of inspecting a sample of the units of product that make up a batch for the purpose of accepting or rejecting the entire batch, as prescribed in the associated pre-established sampling plan