

Performance evaluation of in vitro diagnostic medical devices

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British Standard

ICS 11.100

National foreword

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English version

Performance evaluation of in vitro diagnostic medical devices

Détermination des performances des dispositifs médicaux
pour diagnostic in vitro

Leistungsbewertung von In-vitro-Diagnostika

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

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Foreword

This document EN 13612:2002 has been prepared by Technical Committee CEN/TC 140 "In vitro diagnostic medical devices", the secretariat of which is held by DIN.

The European Diagnostic Manufacturers Association (EDMA) has contributed to its preparation.

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of an identical text or by endorsement, at the latest by September 2002, and conflicting national standards shall be withdrawn at the latest by September 2002.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.

Annex ZA is for information only.

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.

Introduction

Directive 98/79/EC on in vitro diagnostic medical devices (IVD MDs) requires in Annex III, section 3, indent 11 and section 6.1, in Annex IV, section 3.2 c) and in Annex V, section 3, that the manufacturer provides evidence in his technical documentation that the IVD MD performs as claimed, whether these claims are of a technical, analytical or diagnostic nature. Such evidence can be shown by data already available to the manufacturer or by scientific literature or by data originating from performance evaluation studies in a clinical or other appropriate environment in accordance with the intended use.

If a performance evaluation study is necessary and appropriate to support performance claims of the IVD MD, this standard describes how the manufacturer can fulfil his obligation to conduct a scientifically sound performance evaluation study. The evaluation plan is adapted to the nature of the IVD MD and its intended use, taking into account the various recommendations given in standards and scientific literature.

Considering the broad range of IVD MDs covered by Directive 98/79/EC and taking into account that, up to now, there is no uniformly applicable document, it is the purpose of this standard to present the common elements to be considered for a performance evaluation. The applicability of many items described will depend on the level of complexity of the IVD MD.

At the time of drafting this standard it was envisaged that the European Commission would publish a number of Common Technical Specifications (CTSs) which would be relevant to Directive 98/79/EC on in vitro diagnostic medical devices. It was further envisaged that these would be referenced in the Official Journal of the European Communities. In particular these CTSs will apply to in vitro diagnostic medical devices falling into list A of annex II of the Directive 98/79/EC and possibly a number of in vitro diagnostic medical devices in list B of annex II of the same directive. Manufacturers should therefore take these CTSs into account within the context of Article 5 "Reference to standards", of the Directive 98/79/EC.