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Surface chemical analysis — Characterization of functional glass substrates for biosensing applications

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National foreword

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 201, *Surface chemical analysis*.

Introduction

Sensing devices based on immobilized biomolecules on solid substrates are a steadily growing market in personalized medicine and point of care (POC) diagnostics, which are becoming tremendously important for our society. Precise knowledge of these biointerfaces is a prerequisite for a reliable and proper functionality of such biosensing devices. This kind of knowledge includes surface composition, surface chemistry (e.g. functional groups, surface species), surface structure/morphology, in-depth compositional profiles and film thickness, which can be obtained by a thorough physico-chemical characterization using surface chemical analysis.

This report on surface chemical analysis of glass substrates for biosensors prepared by ISO/TC 201/WG 4 has been prepared in coordination with the overall characterization needs identified by experts in TC 201.

This document describes the information that can be obtained by the different analytical techniques and examines how this information can be used to understand and solve important questions and challenges in the biosensor production process.

With that focus, consideration of

— bulk composition;

— surface composition;

— cleanliness;

— wettability;

— reactivity; and

— stability

are relevant and (in an ideal case) should be known for each component, i.e. substrate, functional coating/layer and biomolecular probes, of a reliable biosensing device.

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Surface chemical analysis — Characterization of functional glass substrates for biosensing applications

1 Scope

This document gives examples of how methods of surface chemical analysis in the scope of ISO TC 201 are useful to characterize the nature of substrates used to produce biosensing devices. Successful characterization will give the opportunity for a better understanding of aspects of surface chemistries and reactions at each step of production influencing the overall performance of the final device, for example a microarray. The steps of preparation are the activation of the substrate by immobilization of linker molecules and the functionalization of the activated substrate with biomolecules required for specific biosensing, the so-called probes.

Herein, a focus is set on silane-based functionalization of glass slides, a critical production step for subsequent immobilization of probe molecules. Those probes are used for sensing of biological recognition events. The silanization process has been selected because it is one of the most popular in biosensor production today.

This document gives an overview of methods, strategies and guidance to identify possible sources of problems related to substrates, device production steps (cleaning, activation and chemical modification) and shelf-life (storage conditions and ageing). It is particularly relevant for surface chemical analysts characterizing glass-based biosensors, as well as developers or quality managers in the biosensing device production community. Based on quantitative and qualitative surface chemical analysis, strategies for identifying the cause of poor performance during device manufacturing can be developed and implemented. This document shows how far the light may shine today and possible starting points for more specific activities of ISO/TC 201 in the future, which end in standardized procedures for measurements.

No specific protocols on processing are discussed in this document. To learn more about protocols the reader is referred to specialized literature, see for example References [1] to [9].

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 18115-1:2013*Surface chemical analysis — Vocabulary — Part 1: General terms and terms used in spectroscopy*

ISO 18115-2:2013*Surface chemical analysis — Vocabulary — Part 2: Terms used in scanning-probe microscopy*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18115-1:2013 and ISO 18115-2:2013 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/