BS ISO 18385:2016

BSI Standards Publication

Minimizing the risk of human DNA contamination in products used to collect, store and analyze biological material for forensic purposes — Requirements

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National foreword

This British Standard is the UK implementation of ISO 18385:2016.

The UK participation in its preparation was entrusted to Technical Committee FSM/1, Forensic Science Processes.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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INTERNATIONAL STANDARD

ISO 18385

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Minimizing the risk of human DNA contamination in products used to collect, store and analyze biological material for forensic purposes — Requirements

Réduire au maximum le risque de contamination de l'ADN dans les produits utilisés pour recueillir et analyser du matériel biologique en criminalistique — Exigences

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Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
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Contents

Page

Foreword ... **iv**
Introduction ... **v**
1 Scope ... **1**
2 Terms and definitions ... **2**
3 Abbreviated terms ... **5**
4 Types of products ... **5**
4.1 General ... 5
4.2 Products that come into direct contact with biological stains or material potentially containing human DNA ... 5
4.3 Chemicals, reagents, solvents, and some disposables involved in the analysis of human DNA ... 6
4.4 Protective barrier products that are used during the collection and analysis of biological material ... 6
5 Quality management systems ... **6**
5.1 General ... 6
5.2 Documents and records ... 6
5.3 Authorization ... 7
5.4 Subcontracting of work and purchase of components ... 7
5.5 Control of nonconforming product ... 7
5.6 Corrective and preventive action ... 8
5.7 Staff contamination detection provision ... 8
6 Human DNA contamination risk management ... **8**
6.1 General ... 8
6.2 Risk assessment ... 8
6.3 Risk mitigation ... 10
6.4 Risk control measures ... 10
6.4.1 Equipment ... 10
6.4.2 Personnel ... 10
6.4.3 Cleaning and maintenance ... 10
7 Environmental human DNA monitoring ... **11**
8 Requirements for products subject to post-production treatment ... **11**
9 Requirements for products not subject to post-production treatment ... **12**
9.1 Product testing ... 12
9.2 Batch records ... 12
10 Product packaging, labelling, and documentation ... **12**
Annex A (normative) **Compliance testing** ... **13**
Annex B (informative) **Guidance on the effectiveness of post-production treatments currently used in the manufacture of products** ... **15**
Annex C (informative) **Relevant markers for DNA profiling** ... **17**
Bibliography ... **18**

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 272, *Forensic sciences*.

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Introduction

This International Standard was produced with the aim to create global standards for manufacturers of forensic products used in human DNA analysis. Inadvertent contamination by manufacturers of consumables and reagents, when combined with the improved sensitivity of DNA testing methods, increasingly interferes with forensic analysis.

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INTERNATIONAL STANDARD ISO 18385:2016(E)

Minimizing the risk of human DNA contamination in products used to collect, store and analyze biological material for forensic purposes — Requirements

WARNING — This International Standard calls for the use of procedures that may be a health hazard or cause injury if adequate precautions are not taken.

1 Scope

This International Standard specifies requirements for the production of products used in the collection, storage, and analysis of biological material for forensic DNA purposes, but not those consumables and reagents used in post-amplification analysis.

The consumables and reagents covered by this International Standard include those used for evidence collection (sampling kits), such as swabs, containers, and packaging, and also products used in the analysis of DNA samples, such as tubes and other plasticware, disposable laboratory coats, gloves, and other consumables.

This International Standard applies to the production of consumables and reagents which do not require cleaning for continued use. This International Standard does not cover technical product specifications (i.e. product design).

This International Standard excludes microbiological testing.

This International Standard specifies a requirement for manufacturers to minimize the risk of occurrence of detectable human nuclear DNA contamination in products used by the global forensic community.

An overview of the International Standard is provided in Figure 1.

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