PD ISO/TS 21726:2019

BSI Standards Publication

Biological evaluation of medical devices — Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents

bsi.

National foreword

This Published Document is the UK implementation of ISO/TS 21726:2019.

The UK participation in its preparation was entrusted to Technical Committee CH/194, Biological evaluation of medical devices.

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.

Published by BSI Standards Limited 2019

ISBN 978 0 580 99738 9

ICS 11.100.20

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 28 February 2019.

Amendments/corrigenda issued since publication

Date	Text affected

PD ISO/TS 21726:2019

TECHNICAL SPECIFICATION

ISO/TS 21726

First edition
2019-02-25

Biological evaluation of medical devices — Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents

Évaluation biologique des dispositifs médicaux — Application du seuil de préoccupation toxicologique (TTC) pour évaluer la biocompatibilité des substances extractibles des dispositifs médicaux

Reference number
ISO/TS 21726:2019(E)

COPYRIGHT PROTECTED DOCUMENT

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 194, *Biological and clinical evaluation of medical devices*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Biological evaluation of medical devices — Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents

1 Scope

This document describes the basis for, selection of, and general applicability of a threshold of toxicological concern (TTC) value for a constituent present in/on a medical device or released from a medical device. The TTC values in this document can be used for:

— comparing to a maximum concentration of an identified or unidentified constituent in an extract (see ISO 10993-18);

— supporting toxicological equivalence;

— comparing to a maximum exposure dose estimate of an identified constituent (see ISO 10993-17).

NOTE Constituent is defined in 3.1.

ISO 10993-18 specifies how to convert TTC (µg/d) into a concentration (µg/ml).

TTC is not applicable to constituents with adequate toxicity data for deriving a tolerable intake (TI) value (see ISO 10993-17).

The TTC values established in this document are protective for carcinogens, systemic toxicants, and reproductive toxicants (see Clause 5). This document does not include TTC values for other biological endpoints assessed as part of the biological evaluation of a medical device, per ISO 10993-1, for example:

— cytotoxicity;

— irritation;

— sensitization;

— hemocompatibility;

— material mediated pyrogenicity;

— local effects that occur in tissues at the site of contact between a medical device and the body (e.g. the observations from implantation studies).

The TTC values in this document do not apply to potential exposure via gas pathways of medical devices. For application of TTC for constituents present/released from these devices, see the ISO 18562 series.

The TTC values presented in this document are not applicable for the safety assessment of cohort of concern (see 5.3).

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 10993-1:2018, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*