BS EN ISO 16408:2015

BSI Standards Publication

Dentistry — Oral care products — Oral rinses

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National foreword

This British Standard is the UK implementation of EN ISO 16408:2015. It supersedes BS EN ISO 16408:2004 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/106/7, Oral hygiene products.

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

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English Version

Dentistry - Oral care products - Oral rinses (ISO 16408:2015)

Médecine bucco-dentaire - Produits de soins bucco-dentaire - Bains de bouche (ISO 16408:2015)

Zahnheilkunde - Mundhygieneprodukte - Mundspüllösungen und Mundwässer (ISO 16408:2015)

This European Standard was approved by CEN on 10 July 2015.

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European foreword

This document (EN ISO 16408:2015) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 "Dentistry" 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of an identical text or by endorsement, at the latest by March 2016, and conflicting national standards shall be withdrawn at the latest by March 2016.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 16408:2004.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 16408:2015 has been approved by CEN as EN ISO 16408:2015 without any modification.

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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 106, *Dentistry*, Subcommittee SC 7, *Oral care products*.

This second edition cancels and replaces the first edition (ISO 16408:2004), which has been technically revised with the following changes:

— "heavy metals" has been replaced by the term *unintended heavy metals*, which has been defined in 3.3;

— reference to ISO 28888 and corresponding requirement in 5.1 were added;

— ambient storage conditions of real time test for determination of stability against ageing (7.4.1) was changed (23 ± 2) °C at (60 ± 15) % relative humidity;

— the bibliography was updated by including latest ISO/TC 217 standards.

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