



NSAI
Standards

Irish Standard
I.S. EN ISO 16635-2:2014

Dentistry - Dental rubber dam instruments - Part 2: Clamp forceps(ISO 16635-2:2014)

I.S. EN ISO 16635-2:2014

Incorporating amendments/corrigenda/National Annexes issued since publication:

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation — recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):

NOTE: The date of any NSAI previous adoption may not match the date of its original CEN/CENELEC document.

This document is based on:

EN ISO 16635-2:2014

Published:

2014-09-24

*This document was published
under the authority of the NSAI
and comes into effect on:*

2014-10-11

ICS number:

11.060.20

NOTE: If blank see CEN/CENELEC cover page

NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie
W NSAI.ie

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

EUROPEAN STANDARD

EN ISO 16635-2

NORME EUROPÉENNE

EUROPÄISCHE NORM

September 2014

ICS 11.060.20

English Version

**Dentistry - Dental rubber dam instruments - Part 2: Clamp
forceps(ISO 16635-2:2014)**

Médecine bucco-dentaire - Instruments de digue dentaire
en caoutchouc - Partie 2: Pinces porte-crampons (ISO
16635-2:2014)

Zahnheilkunde - Kofferdaminstrumente - Teil 2:
Klammerzangen (ISO 16635-2:2014)

This European Standard was approved by CEN on 28 June 2014.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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 United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

Foreword.....	3
----------------------	----------

Foreword

This document (EN ISO 16635-2:2014) 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 2015, and conflicting national standards shall be withdrawn at the latest by March 2015.

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.

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 16635-2:2014 has been approved by CEN as EN ISO 16635-2:2014 without any modification.

This page is intentionally left blank

INTERNATIONAL STANDARD

**ISO
16635-2**

First edition
2014-09-15

Dentistry — Dental rubber dam instruments —

Part 2: Clamp forceps

*Médecine bucco-dentaire — Instruments de digue dentaire en
caoutchouc —*

Partie 2: Pinces porte-crampons



Reference number
ISO 16635-2:2014(E)

© ISO 2014

ISO 16635-2:2014(E)



COPYRIGHT PROTECTED DOCUMENT

© ISO 2014

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Requirements	2
4.1 General.....	2
4.2 Total length.....	2
4.3 Locking part.....	2
4.4 Distance between the forceps handles in the closed, passive state.....	2
4.5 Retaining pins.....	2
4.6 Spring and ability to return to the original state.....	3
4.7 Materials.....	3
4.8 Surface finish.....	3
4.9 Corrosion resistance and resistance to reprocessing.....	3
5 Test methods	3
5.1 Visual examination.....	3
5.2 Dimensions.....	3
5.3 Reprocessing.....	3
6 Marking	4

ISO 16635-2:2014(E)

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 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 4, *Dental instruments*.

ISO 16635 consists of the following parts, under the general title *Dentistry — Dental rubber dam instruments*:

- *Part 1: Hole punch*
- *Part 2: Clamp forceps*

Introduction

In order to support the increasing use of dental rubber dam the application of dental rubber dam should be supported by standardization of the required instruments and materials.

In dental practice and when used as intended, clamp forceps for dental rubber dam clamps come into contact with the patient.

Dentistry — Dental rubber dam instruments —

Part 2: Clamp forceps

1 Scope

This part of ISO 16635 specifies requirements and test methods for clamp forceps intended for the application of dental rubber dam clamps to teeth.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942, *Dentistry — Vocabulary*

ISO 6507-1, *Metallic materials — Vickers hardness test — Part 1: Test method*

ISO 6508-1, *Metallic materials — Rockwell hardness test — Part 1: Test method*

ISO 16635-1, *Dentistry — Dental rubber dam technique — Part 1: Hole punch*

ISO 15510:2010, *Stainless steels — Chemical composition*

ISO 17664, *Sterilization of medical devices — Information to be provided by the device manufacturer for the processing of reusable medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 16635-1 and the following apply.

3.1

dental rubber dam

rubber dam

dental dam

sheet of elastomeric film composed of natural rubber latex or synthetic material that is used to isolate one or several teeth from the rest of the oral cavity during a dental restorative procedure

3.2

locking part

device located around the parts of the forceps handles near the joint, which locks automatically when the clamp forceps opens, thus fixating the forceps after it has picked up the dental dam clamp

3.3

clamp receiver

working end of the clamp forceps which serves for the picking up and bringing into position of the dental rubber dam clamp and is linked with the forceps joint by means of a connecting piece

Note 1 to entry: The working ends move diametrically opposed to the forceps handles as a result of the handles being guided in the joint.

This is a free preview. Purchase the entire publication at the link below:

[Product Page](#)

-
- Looking for additional Standards? Visit Intertek Inform Infostore
 - Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation
-