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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:*

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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: Pincés porte-crampons (ISO  
16635-2:2014)

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

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**EN ISO 16635-2:2014 (E)**

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## **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of an identical text or by endorsement, at the latest by March 2015, and conflicting national standards shall be withdrawn at the latest by March 2015.

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### **Endorsement notice**

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**Dentistry — Dental rubber dam  
instruments —**

**Part 2:  
Clamp forceps**

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

*Partie 2: Pincés porte-crampons*



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**ISO 16635-2:2014(E)**



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## 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](http://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 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.

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