



NSAI
Standards

Irish Standard
I.S. EN ISO 3665:2013

Photography - Intra-oral dental radiographic film and film packets - Manufacturer specifications (ISO 3665:2011)

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I.S. EN ISO 3665:2013

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English Version

Photography - Intra-oral dental radiographic film and film packets - Manufacturer specifications (ISO 3665:2011)

Photographie - Film et paquets de films pour la
radiographie dentaire intrabuccale - Spécifications (ISO
3665:2011)

Fotografie - Intraorale dentale Röntgenfilme und
Filmpackungen - Herstellerangaben (ISO 3665:2011)

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Foreword

The text of ISO 3665:2011 has been prepared by Technical Committee ISO/TC 42 “Photography” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 3665:2013 by 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of an identical text or by endorsement, at the latest by September 2013, and conflicting national standards shall be withdrawn at the latest by September 2013.

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The text of ISO 3665:2011 has been approved by CEN as EN ISO 3665:2013 without any modification.

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I.S. EN ISO 3665:2013
INTERNATIONAL
STANDARD

ISO
3665

Third edition
2011-09-01

**Photography — Intra-oral dental
radiographic film and film packets —
Manufacturer specifications**

*Photographie — Film et paquets de films pour la radiographie dentaire
intra-buccale — Spécifications*



Reference number
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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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ISO 3665 was prepared by Technical Committee ISO/TC 42, *Photography*, in collaboration with Technical Committee ISO/TC 106, *Dentistry*.

This third edition cancels and replaces the second edition (ISO 3665:1996), which has been technically revised.

The following significant changes have been made from the second edition.

- In 7.2, the elevated temperature storage test and storage abuse test have been removed and replaced by a requirement for manufacturers to clearly stipulate the shipping, handling, and storage conditions required, ensuring that the diagnostic quality of the film is maintained up to the expiry date of the film.
- In 5.2.7, the base plus fog density has been reviewed and a maximum level has been set for the point of manufacture.
- In 5.2.8, the base plus fog density has been reviewed and a maximum has been set for the manufacturer to use in order to set the expiry date of the product.
- In 7.3, in recognition that background radiation can reduce the expiry date of a film, information to this effect has been included.
- In Table 1, the requirements for C speed film have been removed, as use of this film is no longer justified on radiological and clinical grounds.
- In 7.2, the requirements for film sizes have been rationalized to conform with current manufacturing practice.
- In 7.1, no requirement for a colour coding system for films has been included; instead it is the responsibility of the manufacturer to provide a clear explanation in the instructions if a colour coding system is used.
- In 7.1, films requiring the use of an external attenuation device have been included.

Photography — Intra-oral dental radiographic film and film packets — Manufacturer specifications

1 Scope

This International Standard establishes a system for the classification of intra-oral radiographic film by the speed of the film/process system and by the size of the film. It specifies the sensitometric characteristics of the film/process systems, the physical characteristics of the film and packets, and it describes packaging and labelling requirements.

This International Standard is applicable to intra-oral dental radiographic film for manual or automatic processing. It does not apply to films intended to be exposed with fluorescent intensifying screens, or films intended to be viewed primarily by reflected light.

2 Normative references

The following referenced documents are indispensable for the application 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 1, *Geometric Product Specifications (GPS) — Standard reference temperature for geometrical product specification and verification*

ISO 5-2, *Photography and graphic technology — Density measurements — Part 2: Geometric conditions for transmittance density*

ISO 5-3, *Photography and graphic technology — Density measurements — Part 3: Spectral conditions*

ISO 554, *Standard atmospheres for conditioning and/or testing — Specifications*

ISO 5799, *Photography — Direct-exposing medical and dental radiographic film/process systems — Determination of ISO speed and ISO average gradient*

ISO 8374, *Photography — Determination of ISO safelight conditions*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 18906, *Imaging materials — Photographic films — Specifications for safety film*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

expiry date

date, set by the manufacturer, beyond which the manufacturer does not guarantee the quality of the product when handled, shipped and stored according to his instructions

3.2

gray

Gy

dose of X and/or gamma radiation absorbed by 1 kg of air, which imparts 1 J of initial kinetic energy to those charged particles that it produces

NOTE Gy = 1 J/kg of air (equivalent to 114,5 R or to 0,029 5 C/kg).

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