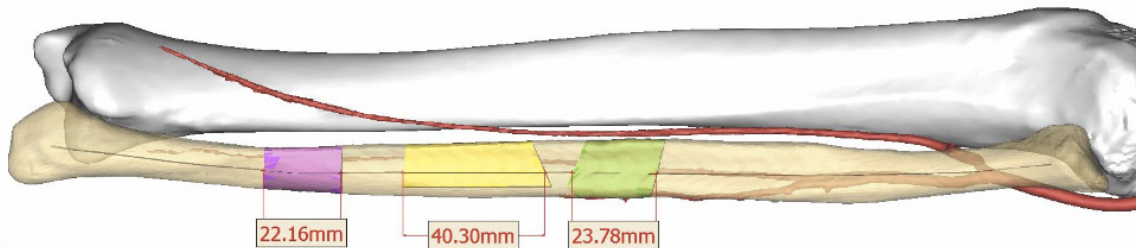
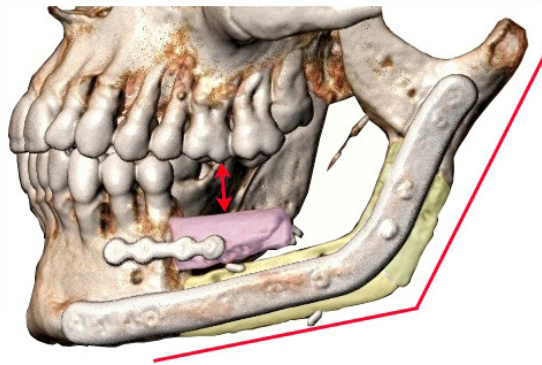


# Journal of Diagnostics and Treatment of Oral and Maxillofacial Pathology

4 2024



The cover images indicate the key direction of the journal and highlight an article titled “The ‘Beveled One-and-a-Half-Barrel’ Fibula Transplant with Virtual Surgical Planning and CT-Guided Implant Surgery for Prosthetic Rehabilitation in Posterior Mandible Defects: A Pictorial Essay” by Olindo MASSARELLI and Silvio Mario MELONI. The article was published in Volume 6, Issue 3.

This is a monthly open access and peer-reviewed journal for oral and maxillofacial surgeons. The journal made the transition from a print and an online version to an online-only version on January 1, 2022.



EDITOR IN CHIEF  
Oleksii Tymofieiev, *Ukraine*



# TANTUM VERDE®

QUICK RELIEF FROM PAIN  
AND INFLAMMATION IN THE  
MOUTH AND THROAT<sup>1</sup>

**AN INTEGRAL COMPONENT OF THE TREATMENT  
OF PAIN AND INFLAMMATION IN THE ORAL CAVITY  
IN 60 COUNTRIES WORLDWIDE!<sup>2</sup>**



Reg. № UA/3920/01/01

**LOCAL ANESTHETIC  
AND ANTI-INFLAMMATORY  
EFFECT<sup>1</sup>**

- **JAWS FRACTURES<sup>3</sup>**
- **IMPLANTS PLACEMENT<sup>4</sup>**
- **WOUNDS OF ORAL CAVITY<sup>5</sup>**



#### SUMMARY OF PRODUCT CHARACTERISTICS

**NAME OF THE MEDICINAL PRODUCT.** Tantum Verde 0.15% mouthwash. **QUALITATIVE AND QUANTITATIVE COMPOSITION.** Each 100 ml contains: active ingredient: benzydamine hydrochloride 0.15 g (equivalent to 0.134 g of benzydamine). **Therapeutic indications.** Treatment of symptoms such as irritation/inflammation including those associated with pain in the oropharyngeal cavity (e.g. gingivitis, stomatitis and pharyngitis), including those resulting from conservative or extractive dental therapy. **Posology and method of administration.** Pour 15 ml of Tantum Verde mouthwash into the measuring cup, 2-3 times per day, using it either at full concentration or diluted. If diluted, add 15 ml of water to the graduated cup. Do not exceed the recommended dosage. **Contraindications.** Hypersensitivity to benzydamine or to any of the excipient. **PHARMACOLOGICAL PROPERTIES. Pharmacodynamic properties.** Pharmacotherapeutic group: Stomatologic drugs: other agents for local oral treatment, ATC code: A01AD02. Clinical studies demonstrate that benzydamine is effective in relieving suffering from localised irritation of the mouth and pharynx. In addition, benzydamine possesses a moderate local anaesthetic effect. **Pharmacokinetic properties. Absorption.** Absorption through the oropharyngeal mucosa is demonstrated by the presence of measurable quantities of benzydamine in human plasma. These levels are insufficient to produce systemic effects. **Distribution.** When applied locally, benzydamine has been shown to accumulate in inflamed tissues where it reaches effective concentrations because of its capacity to penetrate the epithelial lining.

**Information about medicines. Information for health care professionals for use in professional activities.**

1. Інструкція для медичного застосування лікарського засобу Тантум Верде®, розчин для ротової порожнини, РПН № UA/3920/01/01, затверджено Наказом Міністерства охорони здоров'я України № 636 від 01.10.2015.

2. <http://www.angelini-pharma.com/wps/wcm/connect/com/home/Angelini+Pharma+in+the+world/>

3. Тимофеев А.А. и др. "Особенности гигиены полости рта для профилактики воспалительных осложнений при переломах нижней челюсти". Современная стоматология 2015;1(75):52-8.

4, 4.5. Tymofieiev O.O. et al "Prevention of inflammatory complications upon surgeries in maxillofacial region". J Diagn Treat Oral Maxillofac Pathol. 2017;1:105-12.

Clinical and CT images are courtesy of: Ievgen Fesenko (Department of Oral & Maxillofacial Surgery, PHEI "Kyiv Medical University", Kyiv, Ukraine), Oleg Mastakov ("SCIEDECE—Scientific Center of Dentistry & Ultrasound Surgery" Kyiv, Ukraine)



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# About the Journal

APRIL 2024 • VOLUME 8 • ISSUE 4  
[www.dtjournal.org](http://www.dtjournal.org)

## Official Title

*Journal of Diagnostics and Treatment of Oral and Maxillofacial Pathology*

## Official Title in Ukrainian

Журнал діагностики та лікування оральної і щелепно-лицевої патології

## Standard Abbreviation: ISO 4

*J. Diagn. Treat. Oral Maxillofac. Pathol.*

## Acronym

JDTOMP

## International Standard Serial Number (ISSN)

ISSN 2522-1965 (online)

## Aims & Scope

This is a monthly open access and peer-reviewed oral and maxillofacial surgeons. The journal is focused on trauma, microvascular and jaw reconstructive surgery, dental implants, salivary gland tumors/diseases, TMJ lesions, virtual surgical planning, implementation of ultrasonography into the practice of oral and maxillofacial surgeons.

## Editorial Board (EB) Composition

- EB shows significant geographic diversity representing 34 opinion leaders from 14 countries: Brazil, Canada, Colombia, Greece, Hong Kong (SAR, China), India, Israel, Italy, Slovak Republic, Spain, Ukraine, United Arab Emirates, United Kingdom, and United States.
- The majority of the EB Members have a discernible publication history in Scopus, Web of Science, and journals with a high impact factor.
- The publication records of all EB members are consistent with the stated scope and published content of the journal.
- The journal has several full-time professional editors.
- Gender distribution of the editors: 11.76% women (4 persons), 88.24% men (30 persons), 0% non-binary/other, and 0% prefer not to disclose.

## Frequency

12 issues a year (from January 2020)

## Publishing Model

The *Journal of Diagnostics and Treatment of Oral and Maxillofacial Pathology* is a fully online-only open access and peer-reviewed publication.

## Types of Peer Review

The journal employs “double blind” and open reviewing.

## Article Publishing Charge (APC)

The APC in this journal is 500 Euro (\$550 USD) and 250 Euro (\$275 USD)(excluding taxes) depending on the article's type. Details at website: [www.dtjournal.org](http://www.dtjournal.org).

## Types of Articles Currently Published by the Journal

Editorials/Guest Editorials/Post Scriptum Editorials, Images,

Case Reports/Case Series, Original Articles, Review Articles, Discussions, Paper Scans (*synonyms*: Review of Articles, Literature Scan), Book Scans (*synonym*: Book Reviews), Letters to the Editor (*synonym*: Letters), and Viewpoints.

## State Registration in the Ministry of Justice of Ukraine

Registration: Jul 28, 2016 (Certificate: KB № 22251-12151 P)

Re-registration: May 21, 2019 (Certificate: KB № 23999-13839 ПП)

Re-registration: Aug 10, 2021 (Certificate: KB № 24951-14891 ПП).

## State Registration in the National Council of Television and Radio Broadcasting of Ukraine

- The journal is registered as print media (Decision of 2024, April 11, No. 1225). The identifier of print media R30-04318.

- The journal is registered as online media (Decision of 2024, April 25, No. 1454). The identifier of online media R40-04708.

## Journal is Included in

Encyclopedia of Modern Ukraine, Google Scholar, National Repository of Academic Texts, Register of Scientific Publications of Ukraine (also known as Ukrainian Scientific Periodicals or Register of Scientific Professional Publications of Ukraine), ResearchGate, Scilit, and Vernadsky National Library of Ukraine

## Co-Founders

1. Shupyk National Healthcare University of Ukraine (formerly known as Shupyk National Medical Academy of Postgraduate Education).
2. Private Higher Educational Establishment “Kyiv Medical University.”
3. OMF Publishing, Limited Liability Company.

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## Crossref Membership

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10.23999/j.dtomp

## Official Journal of the Association

Ukrainian Association for Maxillofacial and Oral Surgeons

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Website: [www.uamos.org](http://www.uamos.org).

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# TANTUM VERDE®

INFORMATION LEAFLET  
for the medicinal product

## **Composition:**

*active substance:* **benzydamine hydrochloride;**

100 mL of solution contain benzydamine hydrochloride 0.15 g;

*excipients:* ethanol 96%, glycerol, methyl parahydroxybenzoate (E 218), flavor (menthol), saccharin, sodium hydrocarbonate, Polysorbate 20, Quinoline Yellow (E 104), Patent Blue V (E 131), purified water.

**Dosage form.** Oromucosal solution.

*Basic physical and chemical properties:* a clear green liquid with a typical mint flavor.

**Pharmacotherapeutic group.** Dental preparations. Other agents for local oral treatment.

ATC code: A01A D02.

## **Pharmacological properties.**

### *Pharmacodynamics.*

Benzydamine is a non-steroidal anti-inflammatory drug (NSAID) with analgesic and antiexudative properties.

Clinical studies have shown that benzydamine is effective in the relief of symptoms accompanying localized irritation conditions of the oral cavity and pharynx. Moreover, benzydamine has anti-inflammatory and local analgesic properties, and also exerts a local anesthetic effect on the oral mucosa.

### *Pharmacokinetics.*

Absorption through the oral and pharyngeal mucosa has been proven by the presence of measurable quantities of benzydamine in human plasma. However, they are insufficient to produce any systemic pharmacological effect. The excretion occurs mainly in urine, mostly as inactive metabolites or conjugated compounds.

When applied locally, benzydamine has been shown to cumulate in inflamed tissues in an effective concentration

due to its ability to permeate through the mucous membrane.

## **Clinical particulars.**

### **Indications.**

Symptomatic treatment of oropharyngeal irritation and inflammation; to relieve pain caused by gingivitis, stomatitis, pharyngitis; in dentistry after tooth extraction or as a preventive measure.

### **Contraindications.**

Hypersensitivity to the active substance or to any other ingredients of the product.

### **Interaction with other medicinal products and other types of interaction.**

No drug interaction studies have been performed.

### **Warnings and precautions.**

If sensitivity develops with long-term use, the treatment should be discontinued and a doctor should be consulted to get appropriate treatment.

In some patients, buccal/pharyngeal ulceration may be caused by severe pathological processes. Therefore, the patients, whose symptoms worsen or do not improve within 3 days or who appear feverish or develop other symptoms, should seek advice of a physician or a dentist, as appropriate.

Benzydamine is not recommended for use in patients hypersensitive to acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs).

The product can trigger bronchospasm in patients suffering from or with a history of asthma. Such patients should be warned of this.

For athletes: the use of medicinal products containing ethyl alcohol might result in positive antidoping tests considering the limits established by some sports federations.

#### *Use during pregnancy or breast-feeding*

No adequate data are currently available on the use of benzydamine in pregnant and breastfeeding women. Excretion of the product into breast milk has not been studied. The findings of animal studies are insufficient to make any conclusions about the effects of this product during pregnancy and lactation.

The potential risk for humans is unknown.

TANTUM VERDE should not be used during pregnancy or breast-feeding.

#### *Effects on reaction time when driving or using machines*

When used in recommended doses, the product does not produce any effect on the ability to drive and operate machinery.

#### **Method of administration and doses.**

Pour 15 mL of TANTUM VERDE solution from the bottle into the measuring cup and gargle with undiluted or diluted product (15 mL of the measured solution can be diluted with 15 mL of water). Gargle 2 or 3 times daily. Do not exceed the recommended dose.

#### *Children.*

The product should not be used in children under 12 years due to a possibility of ingestion of the solution when gargling.

#### **Overdosage.**

No overdose has been reported with benzydamine when used locally. However, it is known that benzydamine, when ingested in high doses (hundreds times higher than those possible with this dosage form), especially in children, can cause agitation, convulsions, tremor, nausea, increased sweating, ataxia, and vomiting. Such acute overdose requires immediate gastric lavage, treatment of fluid/salt imbalance, symptomatic treatment, and adequate hydration.

#### **Adverse reactions.**

Within each frequency group, the undesirable effects are presented in order of their decreasing seriousness.

Adverse reactions are classified according to their frequency: very common ( $\geq 1/10$ ); common ( $\geq 1/100$  to  $<1/10$ ); uncommon ( $\geq 1/1,000$  to  $<1/100$ ); rare ( $\geq 1/10,000$  to  $<1/1,000$ ); very rare ( $<1/10,000$ ); frequency unknown (cannot be estimated from the available data).

*Gastrointestinal disorders:* rare – burning mouth, dry mouth; *unknown* – oral hypesthesia, nausea, vomiting, tongue edema and discoloration, dysgeusia.

*Immune system disorders:* rare – hypersensitivity reaction, *unknown* – anaphylactic reaction.

*Respiratory, thoracic and mediastinal disorders:* very rare – laryngospasm; *unknown* – bronchospasm.

*Skin and subcutaneous tissue disorders:* uncommon – photosensitivity; very rare – angioedema; *unknown* – rash, pruritus, urticaria.

*Nervous system disorders:* *unknown* – dizziness, headache.

TANTUM VERDE contains methyl parahydroxybenzoate, which can cause allergic reactions (including delayed-type reactions).

**Shelf life.** 4 years.

#### **Storage conditions.**

Do not store above 25°C. Keep out of reach of children.

#### **Packaging.**

120 mL of solution in a bottle with a measuring cup; 1 bottle per cardboard box.

#### **Dispensing category.**

Over-the-counter medicinal product.

#### **Manufacturer.**

Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A., Italy.

Location of the manufacturer and its business address.  
Via Vecchia del Pinocchio, 22 – 60100 Ancona (AN), Italy.

#### **Date of the last revision of the text.**

September 26, 2018.

Information leaflet is

**APPROVED** by

Order of the

**Ministry of Health of Ukraine**

No. 636 dated 01.10.2015

**Registration Certificate**

No. UA/3920/01/01

# State Registration

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про державну реєстрацію  
друкованого засобу масової інформації

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(назва видання іншою мовою (мовами))

Вид видання журнал

(газета, журнал, бюлетень, збірник, альманах, календар, дайджест)

Статус видання вітчизняне

(вітчизняне, спільне)

Мова (мови) видання змішаними мовами: українська, англійська

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за цільовим призначенням наукове, науково-виробниче

(громадсько-політичне, наукове, навчальне, інформаційне,

рекламне (понад 40 відсотків обсягу одного номера – реклама), еротичне тощо)

Обсяг, періодичність 23,1 ум. друк. арк., формат А4 (210x297мм), 1 раз на місяць

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або тематична спрямованість хірургії

Перший заступник Міністра

Євгеній ГОРОВЕЦЬ

10.08.2021  
(дата реєстрації)



**FIGURE.** Certificate of State Re-Registration of the Print Mass Media (journal) in the Ministry of Justice of Ukraine as of 2021. The *Journal* was registered for the first time in 2016 under the title *Diagnostics and Treatment of Oral and Maxillofacial Pathology*. The next re-registration took place in 2019.



# Content

of the Volume 8 • Issue 4 • April 2024

## SECTION BUSINESS EDITORIAL

- A1 **Publisher & Editorial Office Information**
- A2 **Editorial Board**
- A5 **State Registration**
- A6 **Content, Courtesy, & Erratum**
- 33 **The Private Dental Practice in Kyiv, Ukraine: ISO 9001:2015 Certification and Recertification Procedures in 2022-2024**  
Ivan V. Nagorniak



## COURTESY

The *Journal*'s cover images are courtesy Olindo Massarelli, MD, PhD, FEBOMFS.

The images were taken from this article: Massarelli O, Meloni SM. The “beveled one-and-a-half-barrel” fibula transplant with virtual surgical planning and CT-guided implant surgery for prosthetic rehabilitation in posterior mandible defects: a pictorial essay. *J Diagn Treat Oral Maxillofac Pathol* 2022;6(3):39–59.

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SECTION BUSINESS  
EDITORIAL

# The Private Dental Practice in Kyiv, Ukraine: ISO 9001:2015 Certification and Recertification Procedures in 2022-2024

Ivan V. Nagorniak<sup>a,\*</sup>

## ABSTRACT

The development and improvement of the reputation of a private dental practice (PDP) is inextricably linked not only with the provision of dental care to the population, but also with compliance with the best international standards. The purpose of this paper is to highlight the procedure for passing certification and recertification ISO 9001:2015 (ISO 9001) by a PDP in Kyiv, Ukraine. ISO 9001 is a globally recognized standard for quality management developed by the International Organization for Standardization (ISO). The passing of these certifications in Ukraine is of particular interest because they took place under the audit of the certification body from the European Union and in the conditions of the highest complexity, namely the large-scale war of the terrorist state (i.e., Russian Federation) against the Ukrainian state. Our PDP was registered in 2016 and has the legal form of an individual entrepreneur. Individual entrepreneur (transliteration from Ukrainian, *fizychna osoba-pidpnyemets* [FOP]) can also be called as private entrepreneur, sole proprietor, and physical person-entrepreneur. The main economic activity of the presented PDP is stomatological practice (i.e., dental practice). Even though our PDP provides the entire range of dental procedures, its main orientation is oral implantology. The audits and ISO 9001:2015 certifications were conducted in 2022-2024. Detailed data on the completion of two audits is provided and analyzed. The original certificates in two languages, English and Ukrainian, have been added to the article for clarity. The publication also provides step-by-step instructions for checking whether an ISO 9001:2015 certificate is valid on the Internet for both PDP owners and patients. Reflecting after the audits and certifications, I, as the owner of practice, must admit that they significantly

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**Type of article:** editorial

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**Reviewer:**

Vitalii Myroshnychenko,  
Private Dental Practice (Sole Proprietor Myroshnychenko V.O.), Uman,  
Ukraine

The upper image on the right symbolizes that this article contains samples of ISO 9001:2015 certificates issued to a private dental practice in the city of Kyiv, Ukraine.

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improved the practice's organization and allowed it to reach a qualitatively new level. We hope that the details presented in this article will be a guide for other PDP owners in Ukraine and abroad.

### KEY WORDS

Private dental practice (PDP); private stomatological practice; the International Organization for Standardization (ISO); ISO 9001:2015 certification; ISO 9001:2015 recertification; certificate for the management system according to ISO 9001:2015

### INTRODUCTION

*Doctors and dental practitioners have no legal obligation to put a quality system in place, but there can be no doubt about how important is to have one to improve patient satisfaction and heighten the overall prestige of the dental practice.*<sup>1</sup>

—Euronda SpA (joint-stock company)  
Vicenza, Italy

Private dental practice (PDP), which is also known in some countries (Ukraine, etc.) as a private stomatological practice, like other forms of business, is often a lifelong project for the founders. Developing and managing a PDP requires numerous types of licensing, improvements, adherence to certain standards, and investment. Dentists aspire to reach a standard of care that enables them to offer in their practice a service that complies with internationally recognised technological and hygiene requirements.<sup>1</sup> One of the ways to get closer to international standards is to undergo audit and ISO 9001:2015 (ISO 9001) certification. The International Organization for Standardization (ISO) only develops the standards, and certification and recertification are not a requirement.<sup>2</sup> Still, service companies require a document to present to their customers as evidence of ISO 9001 implementation.<sup>2</sup>

Many peer-reviewed articles are devoted to various aspects of PDP.<sup>3–14</sup> However, the search for English-language publications showed a lack of described experience of obtaining ISO certification by the PDPs.

The purpose of this article is to highlight the procedure for passing certification and recertification ISO 9001:2015 (ISO 9001) by a PDP in Kyiv, Ukraine.

### PRACTICE AND ISO CERTIFICATIONS

Our PDP was registered on August 26, 2016, and has the legal form of an individual entrepreneur.<sup>15</sup> Individual entrepreneur (transliteration from

Ukrainian, *fizychna osoba-pidpriemets* [FOP]) can also be called as private entrepreneur, sole proprietor, and physical person-entrepreneur.<sup>16,17</sup> The main economic activity of our business is stomatological practice (i.e., dental practice).<sup>15</sup> The dental practice class according to 2010 Classification of types of economic activities (CTEA) is 86.23.<sup>18</sup> Despite the fact that our PDP provides the entire range of dental procedures, its main orientation is implant dentistry.

It is worth noting that the first ISO certification in the history of our PDP was passed on November 30, 2022 (Fig 1), when Ukraine was repelling the large-scale aggression of the occupying state (i.e., the Russian Federation). The ISO recertification was approved on March 8, 2024 (Fig 2). A comparison of data from the two audits is presented in Table 1.

In the received certificates, it is indicated in two languages, in Ukrainian and in English:

1. The proof of the conforming application with the regulation was furnished and in accordance with the certification procedure it is certified for the company Private Entrepreneur Nagorniak I.V.
2. This certification was conducted in accordance with the TÜV international certification (TIC) auditing and certification procedures and is subject to regular surveillance audits.

Specialists emphasize that, when the audit is over, the PDP will receive its quality certification, which is valid for three years but subject to surveillance audits.<sup>1</sup>

Part of the certification process is the issuance of an audit report, which can be published in two languages, in German language and in Russian language, and nine to ten pages.

According to the PDP audit report, the certificate is used as follows:

- The certificate is posted on the organization's information stand.
- A copy of the certificate is supplied to the



consumer upon request.

- The certificate is applied in accordance with the requirements established in the certification contract.

Our PDP used the services of TÜV Thüringen Ukraine, which is the only branch of the international company TÜV Thüringen on the territory of Ukraine. The official website of the TÜV Thüringen Ukraine is <https://tuv-thuringen.com.ua/>.<sup>19</sup> TÜV Thüringen e.V. (Jena, Germany) is an accreditation body for systems and personnel. The official website of the company is <https://tuev-thueringen.de.><sup>20</sup>

The audit report includes such sections as:

1. Summary assessment.
2. Potential for improvement of the organization's management system.

3. Corrective actions for nonconformities from the previous audit.
4. Nonconformities.
5. Positive aspects.
6. Information about organization.
  - 6.1. Description of the conditions of the organization's location: (1) brief historical background, (2) description of the organization type, (3) regions in which the organization operates or is represented, (4) products (services), and (5) consumers.
  - 6.2. Description of the resources used.
  - 6.3. Changes in the management system since the last audit.
7. Scope of management system.
8. Complaints about the organization's management system.
9. Use of TIC trademark/certificate.

**TABLE 1.** Update of Data from Audits of Private Dental Practice in the City of Kyiv in 2022 and 2024.

#	Audit Data	2022 Audit Report	2024 Audit Report
1	Purpose of the audit	Determining the degree of compliance with the requirements of the standard(s)	Determining the degree of compliance with the requirements of the standard(s)
2	Type of audit	Repeated audit	Certification audit 2nd level
3	Audit criteria	DIN EN ISO 9001:2015 (ISO 9001), TÜV Thüringen certification procedure and other applicable regulations, organization documentation on the management system	DIN EN ISO 9001:2015 (ISO 9001), TÜV Thüringen certification procedure and other applicable regulations, organization documentation on the management system
4	Application area	Private dental practice	Private dental practice
5	Date of the audit	September 14, 2022	January 22, 2024
6	Date of the audit report	September 21, 2022	January 29, 2024
7	Date of approval by the certification body	November 30, 2022	March 8, 2024
8	Audit result	As a result of the achieved audit objectives, it can be recommended to issue a certificate	As a result of the achieved audit objectives, it can be recommended to issue a certificate
9	Certificate registration No.	151001910583	151002411733
10	Audit report No.	3330 2XKG D0	3330/3FYQ/A0



**FIGURE 1.** Certificate for the management system according to ISO 9001:2015 in English (A) and Ukrainian (B). The certificate dated November 30, 2022, attesting to certification of the private dental practice. Private information is closed in dark color. (Fig 1 continued on next page.)

# СЕРТИФІКАТ



## Відповідності системи менеджменту вимогам стандарту ISO 9001:2015

Відповідно до процедури сертифікації підтверджується,  
що підприємство

### ФО-П Нагорняк І.В.

Юридична адреса: █████, м. Київ, вул. Ломоносова, буд. █████,  
кв. █, Україна

Фактична адреса: 01135, м. Київ, вул. Андрющенка, буд. 6г,  
прим. 6, Україна

застосовує систему менеджменту згідно з вищенаведеним  
стандартом у наступних сферах діяльності:


### Приватна стоматологічна практика

Реєстраційний номер  
сертифікату: TIC 15 100 1910583

Чинний до: 2025-06-17  
Дійсний з: 2022-11-30

Звіт про аудит №: 3330 2XKG D0

Сертифікацію проведено відповідно до процедур TIC з аудиту та сертифікації, які передбачають  
проведення періодичних наглядових аудитів.

  
TÜV Thüringen e.V.  
Орган з сертифікації  
систем та персоналу



Єна, 2022-11-30



Без голограми не дійсний.

Чинність сертифіката можна перевірити на сайті [www.tuev-thueringen.de](http://www.tuev-thueringen.de)

Zertifizierungsstelle des TÜV Thüringen e.V. • Ernst-Ruska-Ring 6 • D-07745 Jena • ☎ +49 3641 399740 • ✉ [zertifizierung@tuev-thueringen.de](mailto:zertifizierung@tuev-thueringen.de)

**B**

**FIGURE 1 (continued).** Certificate for the management system according to ISO 9001:2015 in English (A) and Ukrainian (B). The certificate dated November 30, 2022, attesting to re-certification of the private dental practice. Private information is closed in dark color.





**FIGURE 2.** Certificate for the management system according to ISO 9001:2015 in English (A) and Ukrainian (B). The certificate dated March 8, 2024, attesting to re-certification of the private dental practice. Private information is closed in dark color. (Fig 2 continued on next page.)

# СЕРТИФІКАТ



## Відповідності системи менеджменту вимогам стандарту ISO 9001:2015

Відповідно до процедури сертифікації підтверджується,  
що підприємство

### ФО-П Нагорняк І.В.

Юридична адреса: █████, м. Київ, вул. Ломоносова, буд. █████,  
кв. █, Україна

Фактична адреса: 01135, м. Київ, вул. Андрющенка, буд. 6г,  
прим. 6, Україна

застосовує систему менеджменту згідно з вищенаведеним  
стандартом у наступних сферах діяльності:


### Приватна стоматологічна практика

Реєстраційний номер  
сертифікату: 151002411733

Чинний до: 2027-03-07  
Дійсний з: 2024-03-08

Звіт про аудит №: 3330/3FYQ/A0

Сертифікацію проведено відповідно до процедур TIC з аудиту та сертифікації, які передбачають  
проведення періодичних наглядових аудитів.

  
TÜV Thüringen e.V.  
Орган з сертифікації  
систем та персоналу



Єна, 2024-03-08



Без голограми не дійсний.

Чинність сертифіката можна перевірити на сайті [www.tuev-thueringen.de](http://www.tuev-thueringen.de)

Zertifizierungsstelle des TÜV Thüringen e.V. • Ernst-Ruska-Ring 6 • D-07745 Jena • ☎ +49 3641 399740 • ✉ [zertifizierung@tuev-thueringen.de](mailto:zertifizierung@tuev-thueringen.de)

**B**

**FIGURE 2 (continued).** Certificate for the management system according to ISO 9001:2015 in English (A) and Ukrainian (B). The certificate dated March 8, 2024, attesting to re-certification of the private dental practice. Private information is closed in dark color.

## DISCUSSION

*In London, in 1946, 65 delegates from 25 countries meet to discuss the future of international standardization. In 1947, the International Organization for Standardization (ISO) officially comes into existence with 67 technical committees (groups of experts focusing on a specific subject).<sup>21</sup>*  
—History of ISO, an independent, non-governmental international organization

ISO 9001 is a globally recognized standard for quality management.<sup>22</sup> Passing an audit and obtaining ISO 9001:2015 certification by a private practice is a completely voluntary procedure. But it can significantly raise the status of your practice and attract the attention of new clients. So, if the PDP owner has already decided to go this route, there are three steps necessary to obtain a quality system certification<sup>1</sup>:

1. Choosing a consulting agency and drawing up a project plan identifying the objectives to be achieved.
2. Quality improvement in terms of structure, organisation, equipment and technological systems, materials, know-how, and skills.
3. Identifying an accreditation body to audit quality levels and issue the certification.

Among the advantages of obtaining such a certification is that embassies of countries such as Germany, Austria, and Switzerland can be guided when referring patients within Ukraine to clinics that have ISO 9001 certificates issued by certification bodies located in German-speaking states.

The experts note, getting ISO 9001 certification is a long process; it may take a minimum of three to four months to complete the certification process.<sup>2</sup> Anyway, the North American ISO consulting firms emphasize, that ISO 9001 certification is the best and most trusted quality system certification for dentists office.<sup>2</sup>

Figures 3–6 demonstrate how the validity of the PDP certificate can be checked on the German-language website of TÜV Thüringen e.V. (<https://tuev-thueringen.de>).

## CONCLUSIONS

Reflecting after the audits and certifications performed in 2022–2024, I, as the owner of small

PDP, must admit that they significantly improved the practice's organization and allowed it to reach a qualitatively new level. We hope that the details presented in this article will be a guide for other PDP owners in Ukraine and abroad.

*Private dental practices play a crucial role in maintaining the oral and general health of the nation.<sup>8</sup>*

—Catherine Rutland  
Denplan, part of Simplyhealth, Andover, UK

## CONFLICT OF INTEREST

The author declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

## REFERENCES (22)

1. Euronda: improved management in the dental surgery [document on the internet]; Nov 13, 2016 [cited 2024 Apr 16]. Available from: <https://www.euronda.com/news/quality-management-system-in-a-dental-practice/>
2. Limited Management Group Ltd: ISO 9001 certification [document on the internet]; Apr 13, 2024 [cited 2024 Apr 13]. Available from: <https://www.iso-certification.us/iso-9001-certification/service/dentist.html>
3. Garcia RI; Santa Fe Group. The restructuring of dental practice: dentists as employees or owners. *J Am Dent Assoc* **2014**;145(10):1008–10. [https://doi.org/10.1016/s0002-8177\(14\)60160-4](https://doi.org/10.1016/s0002-8177(14)60160-4)
4. Holden ACL, Adam L, Thomson WM. Dentists' perspectives on commercial practices in private dentistry. *JDR Clin Trans Res* **2022**;7(1):29–40. <https://doi.org/10.1177/2380084420975700>
5. Williams RE. Dental practice structure. *J Am Dent Assoc* **2015**;146(5):286–7. <https://doi.org/10.1016/j.adaj.2015.03.002>
6. White JG. Interacting forces influencing private dental practice in South Africa: implications for dental education. *SADJ* **2008**;63(2):080–5.
7. Holden ACL, Adam L, Thomson M. Private practice dentists' views of oral health injustice. *Community Dent Health* **2021**;38(4):268–74. [https://doi.org/10.1922/cdh\\_00009holden07](https://doi.org/10.1922/cdh_00009holden07)
8. Rutland C. The future of private dentistry. *BDJ In Pract* **2021**;34:20–21. <https://doi.org/10.1038/s41404-021-0834-0>
9. Holden ACL, Adam L, Thomson WM. Rationalisation and 'McDonaldisation' in dental care: private dentists'



The screenshot shows the website [tuev-thueringen.de](https://tuev-thueringen.de). The navigation menu includes: MOBILITÄT & VERKEHR, ARBEIT & GESUNDHEIT, GEBÄUDE & ANLAGEN, UMWELT & NACHHALTIGKEIT, ZEICHEN & ZERTIFIKATE (highlighted), UNTERNEHMEN, AKADEMIE, and KARRIERE. The main content area is divided into four columns: PRÜFZEICHEN, ZERTIFIZIERUNGSSTELLE, TÜV ALS MARKE, and FÄLSCHUNGEN. Under 'ZERTIFIZIERUNGSSTELLE', there is a link for 'Zertifikatsgültigkeit'. Below this, the 'TIC TÜV International Certification' section is displayed, featuring the TÜV CERT logo and a paragraph explaining the certification's validity.

**PRÜFZEICHEN**

- Produktprüfungen
- GS-Zeichen
- Zeichen zur Produktprüfung
- Managementsysteme
- Fachbetriebe

**ZERTIFIZIERUNGSSTELLE**

- Personalzertifizierung
- Ihr Weg zum Zertifikat
- Kundeninformation

**TÜV ALS MARKE**

- blueTÜV
- lifeTÜV
- TIC TÜV International Certification

**FÄLSCHUNGEN**

**ZERTIFIKATSGÜLTIGKEIT**

Zertifikatsgültigkeit

**TIC TÜV International Certification**

Als Marke des TÜV Thüringen kennzeichnet **TIC - TÜV International Certification** Zertifikate. Sie dokumentiert, dass ein objektives Audit von einer neutralen und unabhängigen Zertifizierungsstelle erfolgreich durchgeführt wurde. **TÜV International Certification** ist heute ein unverwechselbares Merkmal unserer Zertifikate und führt zur weltweiten Wiedererkennung.

**FIGURE 3.** The validity of the PDP certificate can be checked on the German-language website of TÜV Thüringen e.V. (<https://tuev-thueringen.de>). The letters e.V. (i.e., eingetragener Verein) translated from German as a registered association. To check the validity of a certificate, the visitor needs to go to the Marks and Certificates section (Zeichen and Zertifikate [in German]) and select the Certificate Validity section (Zertifikatsgültigkeit [in German]).

The screenshot shows the website [tuev-thueringen.de](https://tuev-thueringen.de). The header features the TÜV THÜRINGEN logo and a search bar with the placeholder text 'Suchbegriff eingeben...'. The navigation menu includes categories like 'MOBILITÄT & VERKEHR', 'ARBEIT & GESUNDHEIT', 'GEBÄUDE & ANLAGEN', 'UMWELT & NACHHALTIGKEIT', 'ZEICHEN & ZERTIFIKATE', 'UNTERNEHMEN', 'AKADEMIE', and 'KARRIERE'.

## Gültigkeit von Zertifikaten

Die von den Zertifizierungsstellen des TÜV Thüringen ausgestellten Zertifikate attestieren die Einhaltung von Normen und Standards.

Zertifikatsnummer

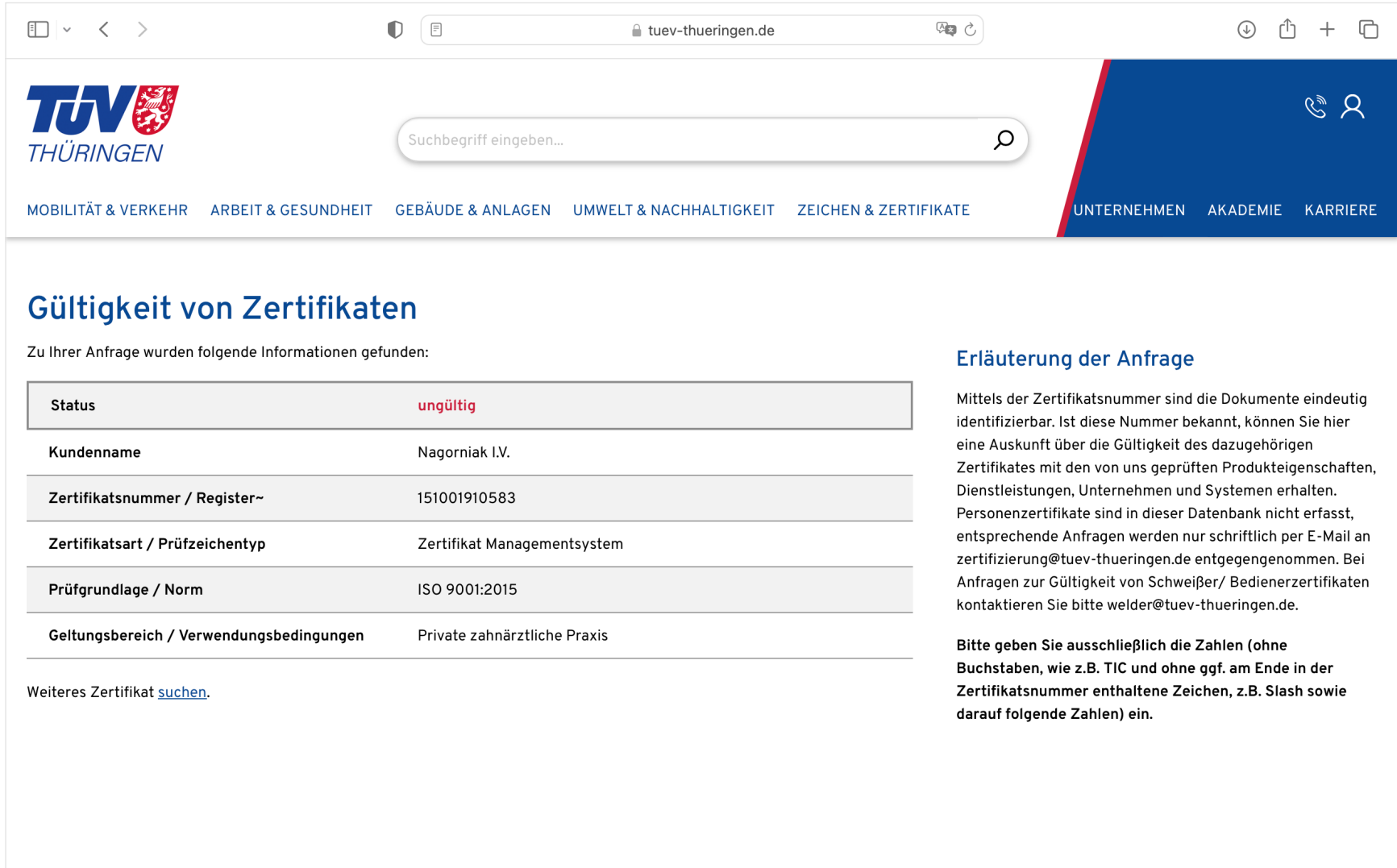
Absenden

### Erläuterung der Anfrage

Mittels der Zertifikatsnummer sind die Dokumente eindeutig identifizierbar. Ist diese Nummer bekannt, können Sie hier eine Auskunft über die Gültigkeit des dazugehörigen Zertifikates mit den von uns geprüften Produkteigenschaften, Dienstleistungen, Unternehmen und Systemen erhalten. Personenzertifikate sind in dieser Datenbank nicht erfasst, entsprechende Anfragen werden nur schriftlich per E-Mail an [zertifizierung@tuev-thueringen.de](mailto:zertifizierung@tuev-thueringen.de) entgegengenommen. Bei Anfragen zur Gültigkeit von Schweißer/ Bedienerzertifikaten kontaktieren Sie bitte [welder@tuev-thueringen.de](mailto:welder@tuev-thueringen.de).

**Bitte geben Sie ausschließlich die Zahlen (ohne Buchstaben, wie z.B. TIC und ohne ggf. am Ende in der Zertifikatsnummer enthaltene Zeichen, z.B. Slash sowie darauf folgende Zahlen) ein.**

**FIGURE 4.** Validity of certificates (Gültigkeit von Zertifikaten [in German]). The certificates issued by the TÜV Thüringen certification bodies attest to compliance with norms and standards. In the line titled Certificate number (Zertifikatsnummer [in German]), you need to enter the corresponding number indicated on the Certificate and click on the Submit (Absenden [in German]) button. The website of TÜV Thüringen e.V.: <https://tuev-thueringen.de>.



The screenshot shows the TÜV Thüringen website interface. At the top, there is a navigation bar with the TÜV Thüringen logo and a search bar. Below the navigation bar, the main content area is titled 'Gültigkeit von Zertifikaten'. Under this title, it states 'Zu Ihrer Anfrage wurden folgende Informationen gefunden:' (The following information was found for your request:). A table displays the certificate details, including the status 'ungültig' (invalid), the customer name 'Nagorniak I.V.', the certificate number '151001910583', the certificate type 'Zertifikat Managementsystem', the certificate basis 'ISO 9001:2015', and the validity area 'Private zahnärztliche Praxis'. To the right of the table, there is a section titled 'Erläuterung der Anfrage' (Explanation of the request) which provides instructions on how to use the certificate number to check its validity. Below this section, there is a note asking the user to provide only numbers and not letters or symbols when entering the certificate number.

**Gültigkeit von Zertifikaten**

Zu Ihrer Anfrage wurden folgende Informationen gefunden:

Status	ungültig
Kundenname	Nagorniak I.V.
Zertifikatsnummer / Register~	151001910583
Zertifikatsart / Prüfzeichentyp	Zertifikat Managementsystem
Prüfgrundlage / Norm	ISO 9001:2015
Geltungsbereich / Verwendungsbedingungen	Private zahnärztliche Praxis

Weiteres Zertifikat [suchen](#).

**Erläuterung der Anfrage**

Mittels der Zertifikatsnummer sind die Dokumente eindeutig identifizierbar. Ist diese Nummer bekannt, können Sie hier eine Auskunft über die Gültigkeit des dazugehörigen Zertifikates mit den von uns geprüften Produkteigenschaften, Dienstleistungen, Unternehmen und Systemen erhalten. Personenzertifikate sind in dieser Datenbank nicht erfasst, entsprechende Anfragen werden nur schriftlich per E-Mail an [zertifizierung@tuev-thueringen.de](mailto:zertifizierung@tuev-thueringen.de) entgegengenommen. Bei Anfragen zur Gültigkeit von Schweißer/ Bedienerzertifikaten kontaktieren Sie bitte [welder@tuev-thueringen.de](mailto:welder@tuev-thueringen.de).

**Bitte geben Sie ausschließlich die Zahlen (ohne Buchstaben, wie z.B. TIC und ohne ggf. am Ende in der Zertifikatsnummer enthaltene Zeichen, z.B. Slash sowie darauf folgende Zahlen) ein.**

**FIGURE 5.** Validity of certificates (Gültigkeit von Zertifikaten [in German]). Certificate status with No. 151001910583: Invalid (ungültig [in German]). The website of TÜV Thüringen e.V.: <https://tuev-thueringen.de>.

**TÜV THÜRINGEN**

Suchbegriff eingeben...

MOBILITÄT & VERKEHR ARBEIT & GESUNDHEIT GEBÄUDE & ANLAGEN UMWELT & NACHHALTIGKEIT ZEICHEN & ZERTIFIKATE UNTERNEHMEN AKADEMIE KARRIERE

## Gültigkeit von Zertifikaten

Zu Ihrer Anfrage wurden folgende Informationen gefunden:

Status	gültig
Kundenname	Einzelunternehmer Nagorniak I.V
Zertifikatsnummer / Register~	151002411733
Zertifikatsgültigkeit (bis)	07.03.2027
Zertifikatsart / Prüfzeichentyp	Zertifikat Managementsystem
Prüfgrundlage / Norm	ISO 9001:2015
Geltungsbereich / Verwendungsbedingungen	Private zahnärztliche Praxis

Weiteres Zertifikat [suchen](#).

### Erläuterung der Anfrage

Mittels der Zertifikatsnummer sind die Dokumente eindeutig identifizierbar. Ist diese Nummer bekannt, können Sie hier eine Auskunft über die Gültigkeit des dazugehörigen Zertifikates mit den von uns geprüften Produkteigenschaften, Dienstleistungen, Unternehmen und Systemen erhalten. Personenzertifikate sind in dieser Datenbank nicht erfasst, entsprechende Anfragen werden nur schriftlich per E-Mail an [zertifizierung@tuev-thueringen.de](mailto:zertifizierung@tuev-thueringen.de) entgegengenommen. Bei Anfragen zur Gültigkeit von Schweißer/ Bedienerzertifikaten kontaktieren Sie bitte [welder@tuev-thueringen.de](mailto:welder@tuev-thueringen.de).

**Bitte geben Sie ausschließlich die Zahlen (ohne Buchstaben, wie z.B. TIC und ohne ggf. am Ende in der Zertifikatsnummer enthaltene Zeichen, z.B. Slash sowie darauf folgende Zahlen) ein.**

**FIGURE 6.** Validity of certificates (Gültigkeit von Zertifikaten [in German]). Certificate status with No. 151002411733: Valid (gültig [in German]). The website of TÜV Thüringen e.V.: <https://tuev-thueringen.de>.



- experiences working in corporate dentistry. *Br Dent J* 2021 Jun 25.  
<https://doi.org/10.1038/s41415-021-3071-3>
10. Nagorniak IV. Managing private practice in a war zone. *J Diagn Treat Oral Maxillofac Pathol* 2022;6(3):35–6.  
<https://doi.org/10.23999/j.dtomp.2022.3.1>
  11. Koba NM, Nagorniak IV. One million dollar private practice. *J Diagn Treat Oral Maxillofac Pathol* 2022;6(2):30–1.  
<https://doi.org/10.23999/j.dtomp.2022.2.2>
  12. Gillette J, Matthews JD, Frantsve-Hawley J, Weyant RJ. The benefits of evidence-based dentistry for the private dental office. *Dent Clin North Am* 2009;53(1):33–45, viii.  
<https://doi.org/10.1016/j.cden.2008.09.002>
  13. Hare K, Yadev N, Campbell C. Initiating research in a private dental practice. *Br Dent J* 2018;224(7):487–9.  
<https://doi.org/10.1038/sj.bdj.2018.228>
  14. Tuominen R, Palmujoki J. Perceived competition in private dental practice in Finland. *Acta Odontol Scand* 2000;58:213–216.  
<https://doi.org/10.1080/000163500750051764>
  15. Sole proprietor Nagorniak I.V. [document on the internet]; Apr 16, 2024 [cited 2024 Apr 16]. Available from:  
[https://youcontrol.com.ua/en/catalog/fop\\_details/65540991/](https://youcontrol.com.ua/en/catalog/fop_details/65540991/)
  16. Koba NM, Nagorniak IV. Ukraine: legal forms for private practice in oral surgery and dentistry. *J Diagn Treat Oral Maxillofac Pathol* 2021;5(9):97–8.  
<https://doi.org/10.23999/j.dtomp.2021.9.1>
  17. Sole proprietor Kosteichuk O.M. [document on the internet]; Apr 12, 2024 [cited 2024 Apr 12]. Available from:  
[https://youcontrol.com.ua/en/catalog/fop\\_details/33902666/](https://youcontrol.com.ua/en/catalog/fop_details/33902666/)
  18. CTEA-2010: class 86.23 (in Ukrainian) [document on the internet]; Apr 10, 2024 [cited 2024 Apr 10]. Available from:  
[https://kved.ukrstat.gov.ua/KVED2010/86/KVED10\\_86\\_23.html](https://kved.ukrstat.gov.ua/KVED2010/86/KVED10_86_23.html)
  19. TÜV Thüringen Ukraine [document on the internet]; Apr 14, 2024 [cited 2024 Apr 14]. Available from:  
<https://tuv-thuringen.com.ua/uk/>
  20. TÜV Thüringen e.V. [document on the internet]; Apr 14, 2024 [cited 2024 Apr 14]. Available from:  
<https://tuev-thuringen.de>
  21. About ISO [document on the internet]; Apr 5, 2024 [cited 2024 Apr 5]. Available from:  
<https://www.iso.org/about-us.html>
  22. ISO 9001:2015: quality management systems: requirements [document on the internet]; Apr 5, 2024 [cited 2024 Apr 5]. Available from:  
<https://www.iso.org/standard/62085.html>



СЕКЦІЯ «БІЗНЕС»  
РЕДАКЦІЙНА СТАТТЯ

UKRAINIAN LANGUAGE

## Приватна стоматологічна практика в Києві, Україні: процедури сертифікації та ресертифікації ISO 9001:2015 в 2022-2024 роках

Іван Нагорняк<sup>а,\*</sup>

### АНОТАЦІЯ

Розвиток і підвищення репутації приватної стоматологічної практики (ПСП) нерозривно пов'язане не тільки з наданням стоматологічної допомоги населенню, а й з дотриманням найкращих світових стандартів. Метою цієї роботи є висвітлення процедури проходження сертифікації та повторної сертифікації ISO 9001:2015 (ISO 9001) ПСП у Києві, Україні. ISO 9001 — це всесвітньо визнаний стандарт управління якістю, розроблений Міжнародною організацією зі стандартизації (ISO – акронім англійською мовою). Проходження цих сертифікацій в Україні становить особливий інтерес, оскільки вони проходили під аудитом сертифікаційного органу з Європейського Союзу та в умовах найвищої складності, а саме широкомасштабної війни терористичної держави (тобто Російської Федерації) проти української держави. Наша ПСП зареєстрована в 2016 році та має організаційно-правову форму фізична особа-підприємець (ФОП). Фізична особа-підприємець англійською мовою може мати різні назви, а саме individual entrepreneur, private entrepreneur, sole proprietor та physical person-entrepreneur. Основним видом економічної діяльності представленої в даній статті ПСП є стоматологічна практика. Незважаючи на те, що наш ПСП надає весь спектр стоматологічних процедур, основним її напрямком є оральна імплантологія. Аудити та сертифікація ISO 9001:2015 проводилися в 2022-2024 роках. Надано та проаналізовано детальні дані про проходження двох аудитів. Для наочності в статтю додано оригінали сертифікатів двома мовами англійською та українською. Стаття також містить покрокові

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Верхнє зображення праворуч символізує, що ця стаття містить зразки сертифікатів ISO 9001:2015, виданих приватній стоматологічній практиці в місті Києві, Україні.

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інструкції щодо перевірки дійсності сертифіката ISO 9001:2015 в Інтернеті як для власників ПСП, так і для пацієнтів. Розмірковуючи про проведені аудити та сертифікації, я, як власник практики, мушу визнати, що вони значно підвищили рівень організації практики та дозволили їй вийти на якісно новий рівень. Сподіваємося, що викладені в цій статті подробиці стануть дороговказом для інших власників ПСП в Україні та за кордоном.

### КЛЮЧОВІ СЛОВА

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