

SECTION BUSINESS EDITORIAL

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

Ivan V. Nagorniak^{a,*}

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-pidpryiemets [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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Reviewer:

Vitalii Myroshnychenko, Private Dental Practice (Sole Proprietor Myroshnychenko V.O.), Uman, Ilkraine 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.\(^1\)

—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.1 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.² Still, service companies require a document to present to their customers as evidence of ISO 9001 implementation.²

Many peer-reviewed articles are devoted to various aspects of PDP.^{3–14} 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.¹⁵ Individual entrepreneur (transliteration from

Ukrainian, fizychna osoba-pidpryiemets [FOP]) can also be called as private entrepreneur, sole proprietor, and physical person-entrepreneur. The main economic activity of our business is stomatological practice (i.e., dental practice). The dental practice class according to 2010 Classification of types of economic activities (CTEA) is 86.23. 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.¹

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/.¹⁹ 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.²⁰

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





for the management system according to ISO 9001:2015

The proof of the conforming application with the regulation was furnished and in accordance with certification procedure it is certified for the company

Private entrepreneur Nagorniak I.V.

Legal address: Lomonosova str., Kyiv, Ukraine Actual address: 6G/6, Andruschenka str., 01135, Kyiv, Ukraine

Scope

Private dental practice

Certificate Registration No.: TIC 15 100 1910583 Valid until: 2025-06-17 Valid from: 2022-11-30

Audit Report No.: 3330 2XKG D0

This certification was conducted in accordance with the TIC auditing and certification procedures and is subject to regular surveillance audits.

TÜV Thüringen e.V.
Certification body for
systems and personnel



Jena, 2022-11-30





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A

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.**)





відповідності системи менеджменту вимогам стандарту ISO 9001:2015

Відповідно до процедури сертифікації підтверджується, що підприємство

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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:
 ТІС 15 100 1910583
 Чинний до: 2025-06-17 Дійсний з: 2022-11-30

Звіт про аудит №: 3330 2XKG D0

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

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



€на, 2022-11-30





Без голограми не дійсний

Чинність сертифіката можна перевірити на сайті <u>www.tuev-thueringen.de</u>

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В

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.

CERTIFICATE



for the management system according to ISO 9001:2015

The proof of the conforming application with the regulation was furnished and in accordance with certification procedure it is certified for the company

Private entrepreneur Nagorniak I.V.

Legal address: Lomonosova str., Lomonosova str., Kyiv, Ukraine Actual address: 6G/6, Andruschenka str., 01135, Kyiv, Ukraine

Scope

Private dental practice

Certificate Registration No.: 151002411733 Valid until: 2027-03-07 Valid from: 2024-03-08

Audit Report No.: 3330/3FYQ/A0

This certification was conducted in accordance with the TIC auditing and certification procedures and is subject to regular surveillance audits.

TÜV Thüringen e.V. Certification body for systems and personnel



Jena, 2024-03-08





Original certificates are branded with a hologram.

The current validity can be demanded at our homepage www.tuev-thueringen.de.

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A

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

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кв. , Україна

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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 ТІС з аудиту та сертифікації, які передбачають проведення періодичних наглядових аудитів.

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



Єна, 2024-03-08



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Чинність сертифіката можна перевірити на сайті <u>www.tuev-thueringen.de</u>

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В

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 standartization. In 1947, the International Organization for Standardization (ISO) officially comes into existance with 67 technical committees (groups of experts focusing on a specific subject). History of ISO, an independent, non-governmental international organization

ISO 9001 is a globally recognized standard for quality management.²² 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 certification¹:

- 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.² Anyway, the North American ISO consulting firms emphasize, that ISO 9001 certification is the best and most trusted quality system certification for dentists office.²

Figures 3–6 demonstrate how the validity of the PDP certificate can be checked on the Germanlanguage 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.⁸
—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.

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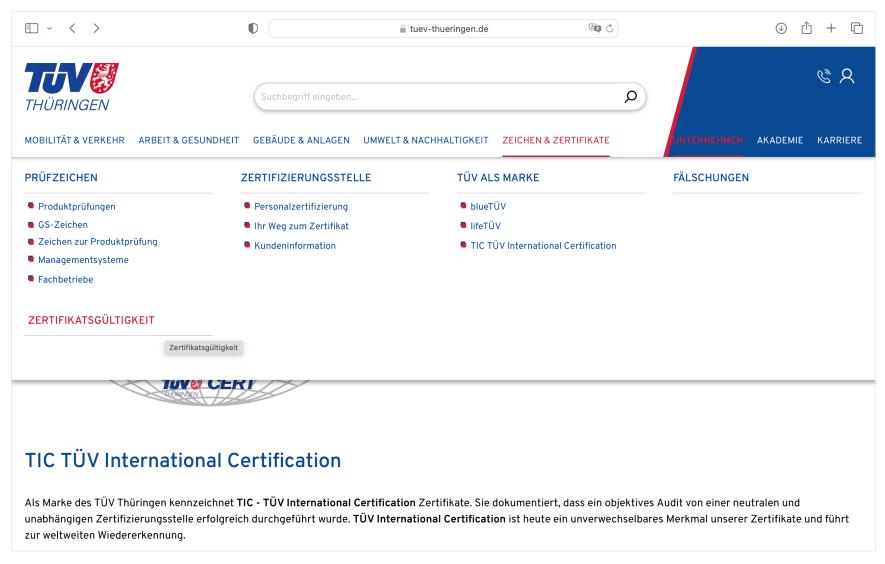


FIGURE 3. The validity of the PDP certificate can be checked on the German-language website of TÜV Thüringen e.V. (https://tuev-thueringen.de). The letters e.V. (i.e., eingetragener Verein) translated from German as a registered association. To check the validity of a certificate, the visitor needs to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

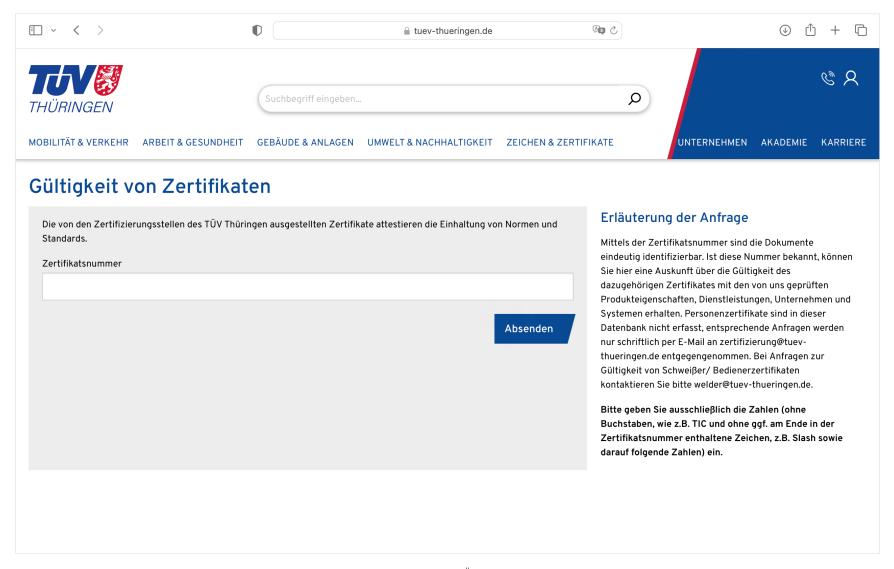


FIGURE 4. Validity of certificates (Gültigkeit von Zertifikaten [in German]). The certificates issued by the TÜV Thüringen certification bodies attest to compliance with norms and standards. In the line titled Certificate number (Zertifikatnummer [in German]), you need to enter the corresponding number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

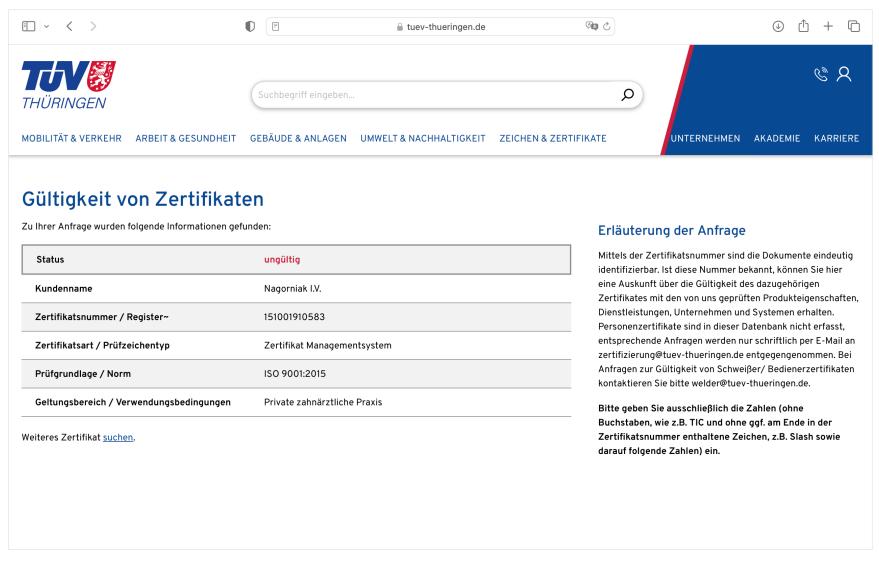
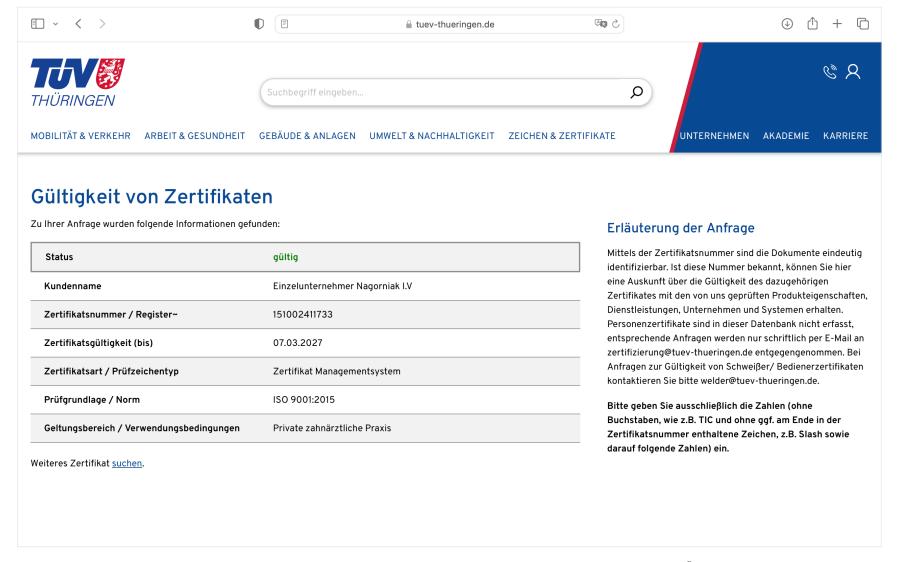


FIGURE 5. Validity of certificates (Gültigkeit von Zertifikaten [in German]). Certificate status with No. 151001910583: Invalid (ungültig [in German]). The website of TÜV Thüringen e.V.: https://tuev-thueringen.de.



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СЕКЦІЯ «БІЗНЕС» РЕДАКЦІЙНА СТАТТЯ

UKRAINIAN LANGUAGE

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

Іван Нагорняка,*

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, a came individual entrepreneur, private entrepreneur, sole proprietor та physical person-entrepreneur. Основним видом економічної діяльності представленої в даній статті $\Pi C\Pi \in \mathsf{стоматологічна}$ 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

Тип статті: редакційна стаття.

Для цитування: Nagorniak IV. The private dental practice in Kyiv, Ukraine: ISO 9001:2015 certification and recertification procedures in 2022-2024. J Diagn Treat Oral Maxillofac Pathol 2024;8(4):33–47.

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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

Приватна стоматологічна практика; фізична особа-підприємець (ФОП); міжнародна організація стандартизації (ISO – акронім англійською мовою); сертифікація ISO 9001:2015; повторна сертифікація ISO 9001:2015; ресертифікація ISO 9001:2015; сертифікат відповідності системи менеджменту вимогам стандарту ISO 9001:2015