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GLOBAL TRADE POLICY IN THE MEDICAL DEVICES AND EQUIPMENT SECTOR: CASE STUDIES ON TRADE-DISPUTE ANALYSIS OF ORTHO-K LENS IMPORTS FROM SOUTH KOREA TO THE EU

ГЛОБАЛЬНА ТОРГОВЕЛЬНА ПОЛІТИКА В СЕКТОРІ МЕДИЧНИХ ЗАСОБІВ ТА ПРИЛАДІВ: КЕЙСИ ЩОДО АНАЛІЗУ ТОРГОВЕЛЬНИХ СПОРІВ ВІДНОСНО ІМПОРТУ ЛІНЗ ORTHO-K З ПІВДЕННОЇ КОРЕЇ ДО ЄС

Olha Yatsenko
Doctor of Sciences (Economics), Professor, Professor of the International Trade and Marketing Department, Kyiv National Economic University named after Vadym Hetman,
e-mail: yacenkoolgakneu@gmail.com
ORCID ID: https://orcid.org/0000-0003-4399-2217

Oleksandr Iatsenko
Ph.D. in Economics, doctoral student of the International Trade and Marketing Department, Kyiv National Economic University named after Vadym Hetman, Seeds Senior Finance Partner Ukraine at Syngenta LLC,
e-mail: om.iatsenko@gmail.com
ORCID ID: https://orcid.org/0000-0002-0388-728X

Anna Sysoieva
Head of Procurement (International Import), «3NRG GmbH» (Germany),
e-mail: anny.sysoieva51@gmail.com
ORCID ID: https://orcid.org/0009-0005-8864-957X

Oleg Sigodzinskyi
Financial controller and CFO (Full), LLC «MEDILENS»,
e-mail: oleg_sig@gmail.com

Ольга Яценко
доктор економічних наук, професор, професор кафедри міжнародної торгівлі і маркетингу, Київський національний економічний університет ім. В. Гетьмана,
e-mail: yacenkoolgakneu@gmail.com
ORCID ID: https://orcid.org/0000-0003-4399-2217

Олександр Яценко
кандидат економічних наук, докторант кафедри міжнародної торгівлі і маркетингу, Київський національний економічний університет ім. В. Гетьмана, старший фінансовий бізнес-партнер (Syngenta LLC),
e-mail: e-mail: om.iatsenko@gmail.com
ORCID ID: https://orcid.org/0000-0002-0388-728X

Анна Сисоєва
керівник відділу закупівель (міжнародний імпорт), «3NRG GmbH» (Німеччина),
e-mail: anny.sysoieva51@gmail.com
ORCID ID: https://orcid.org/0009-0005-8864-957X

Олег Сігодзінський
фінансовий контролер та генеральний директор (повна форма), ТОВ «МЕДІЛЕНС»,
e-mail: oleg_sig@gmail.com

Abstract. *The article aims to identify key regulatory trends, risks, and resolution mechanisms in the international trade of orthokeratology (Ortho-K) lenses, focusing on production discipline and trade compliance in the European Union. It is determined that the current expansion of Ortho-K trade is associated with the increasing demand for non-surgical myopia correction and rapid technological development in South Korea. It is argued that international trade in Ortho-K lenses is becoming a vital component of the cross-border medical devices sector and will continue to develop in light of rising youth myopia rates and the preference for reversible vision correction solutions. However, the industry must overcome significant challenges to sustain growth. These include technical compliance with EU Medical Device Regulations (MDR), alignment with international standards (ISO 13485,*

CE marking), and adherence to ethical production practices as required by Trade and Sustainable Development (TSD) chapters of free trade agreements. Based on theoretical and empirical generalizations, the article concludes that Ortho-K lenses have strong explicit and latent potential in the European market, particularly for pediatric and occupational use. Still, trade discipline is likely to intensify in the form of safety recalls and labour compliance investigations. The study emphasizes that successful market integration depends on a country's ability to meet not only product safety and performance requirements, but also evolving expectations for social responsibility and sustainable production. Two disciplinary cases involving Lucid Korea's trade with EU partners are used to illustrate these dynamics in practice.

Keywords: *orthokeratology, Ortho-K lenses, medical device trade, EU–Korea FTA, product compliance, ISO 13485, CE marking, trade discipline, sustainable development, technical regulation, non-tariff barriers, market access, international trade, labour standards, WTO.*

Анотація. *Метою статті є визначення основних регуляторних тенденцій, ризиків і механізмів врегулювання у сфері міжнародної торгівлі ортокератологічними (Ortho-K) лінзами, з акцентом на виробничу дисципліну та дотримання торгових вимог у Європейському Союзі. Встановлено, що нинішнє розширення торгівлі Ortho-K пов'язане зі зростанням попиту на нехірургічну корекцію міопії та стрімким розвитком технологій у Південній Кореї. Стверджується, що міжнародна торгівля Ortho-K лінзами стає важливим елементом транскордонного ринку медичних виробів і буде надалі розвиватися на тлі зростання дитячої короткозорості та популярності оборотних методів корекції зору. Водночас, для сталого зростання галузі необхідно подолати низку викликів. Серед них – технічна відповідність Регламенту ЄС щодо медичних виробів (MDR), дотримання міжнародних стандартів (ISO 13485, маркування CE), а також забезпечення етичного виробництва згідно з положеннями про торгівлю та сталий розвиток (TSD) угод про вільну торгівлю. На основі теоретичних і емпіричних узагальнень зроблено висновок, що Ortho-K лінзи мають значний явний і прихований потенціал на європейському ринку, особливо для дитячого та професійного використання. Проте дисциплінарні заходи з боку імпортуючих країн можуть посилюватися – зокрема, у формі відкликань продукції або розслідувань щодо умов праці. У дослідженні підкреслюється, що успішна інтеграція на ринку залежить не лише від відповідності технічним і безпековим вимогам, але й від здатності дотримуватися соціальних стандартів та принципів сталого виробництва. Для ілюстрації цих тенденцій розглянуто два кейси торговельної дисципліни між компанією Lucid Korea та її партнерами в ЄС.*

Ключові слова: *ортокератологія, Ortho-K лінзи, торгівля медичними виробами, Угода ЄС–Південна Корея, відповідність продукції, ISO 13485, маркування CE, торговельна дисципліна, сталий розвиток, технічне регулювання, нетарифні бар'єри, доступ до ринку, міжнародна торгівля, трудові стандарти, СОТ.*

Introduction. The theoretical foundations of global trade policy in the medical devices and equipment sector, which gained unprecedented momentum at the beginning of the third millennium, are radically transforming the distribution system of the global economy, establishing a new paradigm in which, on the one hand, the economic and technological dominance of global developed countries is growing, and on the other hand, opportunities are opening up for the formation of new centers of global economic competition. This process is accompanied by the growing influence of global challenges, the failure to take into account the impact of which significantly reduces the efficiency of the functioning of economies and international trade. For Ukraine, which has been affected by challenges related to the pandemic's impact on the healthcare system, it is necessary, from the point of view of realizing national interests and defending state sovereignty, to develop partnerships with countries that are recognized global leaders in the world economy.

The institutional framework for global trade policy in the medical devices and equipment sector has been identified. Traditionally, trade was regulated by bilateral agreements between two countries. After World War II, when free trade became the dominant doctrine, multilateral

agreements such as the GATT and the World Trade Organization (WTO) became the main regime for regulating global trade. However, in the context of the medical devices and equipment sector, it can be said that national medical device registration systems and the World Health Organization play an important role.

Against the backdrop of current trade policy changes, global supply chain disruptions, shifts in countries' positions in the global market, shifts in trade structures, a deepening international division of labor, and increasingly fierce international competition are forcing countries to adopt protectionist measures to stabilize their economies. While every country is willing to offer preferential trade terms, doing so discriminates against its partners. To secure better sales conditions and competitive advantages, countries often resort to various protectionist measures to provoke trade disputes. This issue is of concern because it is unthinkable that world trade would be free of disputes or conflicts among its members. However, particularly in an era of globalization and the development of international relations, competition among these countries has taken on a unique character *(Yacenko 2020; Reznikova N. (2018).*

Vision correction has always played a pivotal role in human development and quality of life–from the invention of rudimentary spectacles in the 13th century to the emergence of laser eye surgery in the 20th century. In recent decades, however, the global increase in myopia, especially among children and adolescents, has driven demand for innovative, non-invasive alternatives to traditional glasses and surgical procedures. One such innovation is orthokeratology (Ortho-K), a method involving the overnight use of specially designed rigid gas-permeable (RGP) lenses that temporarily reshape the cornea to correct vision.

The growing interest in Ortho-K solutions can be attributed to several converging factors. First, rising digital screen use and near-work activities in children have caused a surge in myopia cases worldwide–what the World Health Organization now recognizes as a "myopia epidemic." Second, Ortho-K therapy is increasingly viewed as both a functional vision correction tool and a preventative measure to slow myopic progression. As a result, global markets–particularly in Asia and Europe–are showing rapid adoption of this technology.

Among the global producers of Ortho-K lenses, South Korea stands out for its cutting-edge optical technology, strong clinical research foundations, and rigorous domestic regulation by the Ministry of Food and Drug Safety (MFDS). Lucid Korea Co., Ltd., one of the country's industry leaders, produces lenses that are CE-marked, ISO 13485 certified, and already exported to over 20 countries, including EU member states and Ukraine. Lucid Korea's LK-Lens series represents a benchmark in customizable and pediatric-safe Ortho-K design.

Meanwhile, the European Union has become one of the most promising markets for Ortho-K imports due to its aging population, high public health standards, and active regulatory framework under the Medical Device Regulation (EU MDR 2017/745). Additionally, the EU–South Korea Free Trade Agreement (FTA), in force since 2015, eliminates tariffs on most medical devices, including contact lenses, facilitating smoother entry for Korean exporters.

However, as international trade in Ortho-K lenses expands, new regulatory and policy challenges arise. These include compliance with EU safety and labelling standards, harmonization with ISO norms, and broader trade-related obligations such as labor standards under Trade and Sustainable Development (TSD) chapters. To fully realize the global potential of Ortho-K technologies, exporting countries like South Korea must continuously adapt their quality management systems, address non-tariff barriers, and align production practices with evolving EU norms.

A comprehensive analysis of the Ortho-K sector reveals both significant opportunity and underlying complexity. Market growth is being driven by demand, but also constrained by the need for conformity assessment, post-market surveillance, and the geopolitics of trade. As with other high-tech medical sectors, success in Ortho-K trade depends not only on innovation but also on navigating the intricate web of international economic diplomacy and regulatory compliance.

The purpose of this article is to investigate and systematize the disciplinary mechanisms applied in the context of international trade in medical devices, using the case of orthokeratology (Ortho-K) lenses imported from South Korea to the European Union. The study aims to analyze how trade disputes can arise due to non-compliance with technical standards, regulatory frameworks, and ethical production practices. By presenting two hypothetical but realistic trade-conflict cases, the

article seeks to highlight the role of regulatory diplomacy, the enforcement of EU medical device regulations, and the implications of trade and sustainable development (TSD) provisions embedded in the EU–Korea Free Trade Agreement. The research contributes to a broader understanding of how non-tariff measures, such as product recalls or labor rights monitoring, influence market access, business strategies, and bilateral trade relations in high-tech medical sectors.

Literature review. Orthokeratology, or Ortho-K, is gaining unprecedented momentum in the field of vision correction and preventative eye care. Originally developed in the mid-20th century, the technique has matured significantly through advances in gas-permeable lens technology, corneal mapping, and personalized optical design (Smith & Walline, 2018). Today, Ortho-K is recognized not only as an alternative to glasses and LASIK surgery but also as a scientifically supported intervention to slow the progression of myopia, particularly in children and adolescents (Paune et al., 2020).

South Korea has emerged as a technological leader in the production of advanced Ortho-K lenses. Companies such as Lucid Korea have developed multizone lens models–certified under ISO 13485 and CE standards–and demonstrated effectiveness in diverse clinical populations (Lucid Korea Brochure, 2024). The country's robust health-tech ecosystem and proactive regulatory oversight by the Ministry of Food and Drug Safety (MFDS) have further enabled the international competitiveness of Korean manufacturers.

In Europe, Ortho-K lenses are classified as Class IIa medical devices under the EU Medical Device Regulation (MDR 2017/745). This requires compliance with strict conformity assessments, post-market surveillance, and CE certification. The WTO's 2022 report on medical device trade emphasizes the importance of harmonizing regulatory standards to reduce non-tariff barriers and foster trust among trade partners. Standardization efforts–such as ISO 63152 for lens performance and packaging–play a crucial role in facilitating access to EU markets (WTO Report, 2022).

The EU–South Korea Free Trade Agreement (FTA) has provided additional trade momentum by eliminating tariffs on optical goods and streamlining customs procedures. However, the FTA also includes Trade and Sustainable Development (TSD) clauses that introduce non-economic conditions into market access. In 2021, the EU convened a Panel of Experts to address Korea's failure to enforce ILO labor rights–setting a precedent for potential future scrutiny in high-value export sectors like medical optics (European Commission, 2022).

The World Bank's analysis of medical device trade (World Bank, 2023) underscores that while global trade in high-tech health products is expanding, developing countries face challenges related to regulatory infrastructure and certification costs. Similarly, the UL Global Market Access program (UL, 2023) identifies quality assurance and risk management as the two most frequent causes of product rejections in transatlantic medical trade.

Scientific literature also highlights the growing body of clinical and regulatory research surrounding Ortho-K lenses. Studies by Chou et al. (2005) and Smith et al. (2019) confirm the efficacy of Ortho-K in myopia control, while more recent meta-analyses emphasize the need for consistent post-market monitoring of corneal health outcomes (Liu & Wang, 2022). Despite this progress, scholars caution that scaling Ortho-K globally will require not only innovation but also harmonization of ethical production standards, traceability systems, and equitable access frameworks.

In the Ukrainian context, recent academic work (Sysoieva, 2025) has explored the bilateral certification recognition between Ukraine and South Korea, revealing positive examples of regulatory convergence. This cooperation, facilitated through CE-matching policies and mutual recognition of ISO-based conformity documents, has made Ukraine an important emerging market for Korean Ortho-K lenses.

As with the development of the hydrogen economy, the rise of Ortho-K as a global trade product encompasses both economic potential and policy complexity. Its success depends not only on optical performance but also on compliance with multilayered trade regulations, labor practices, and safety norms.

Main results of the research. Ortho-K lenses are experiencing significant global market expansion, driven by rising pediatric myopia, technological advances in lens materials, and increasing clinical acceptance of non-surgical vision correction. The global **orthokeratology lens market** was

valued at approximately **USD 781.6 million** in 2024 and is expected to grow at a compound annual growth rate (CAGR) of over 16% through the late 2020s.

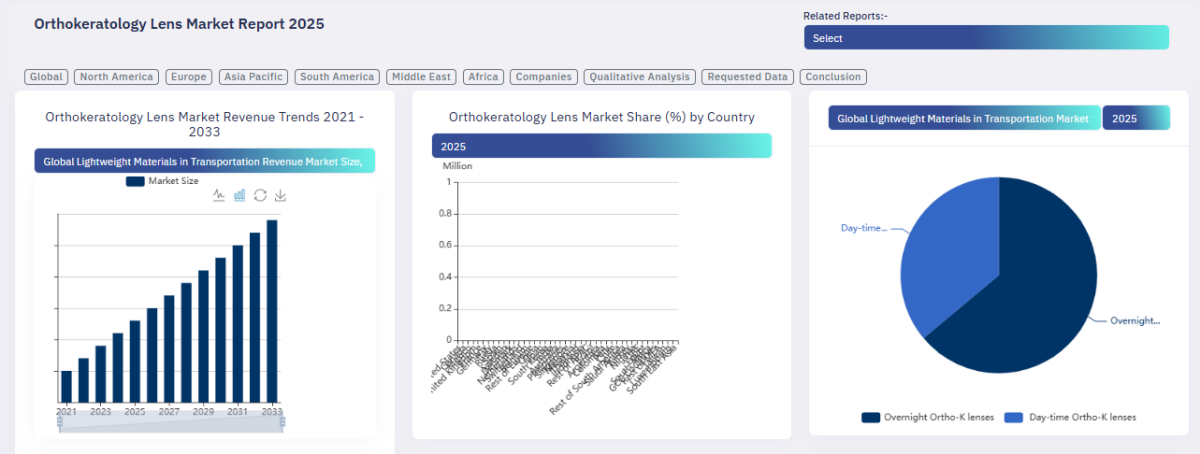

Figure 1. Orthokeratology lens market report, 2021-2033 (*Cognitive market research, 2025*)

Europe accounted for over **30%** of this market, with a regional market size of **USD 234.48 million** in 2024 and projected to continue growing at ~14.7% CAGR.

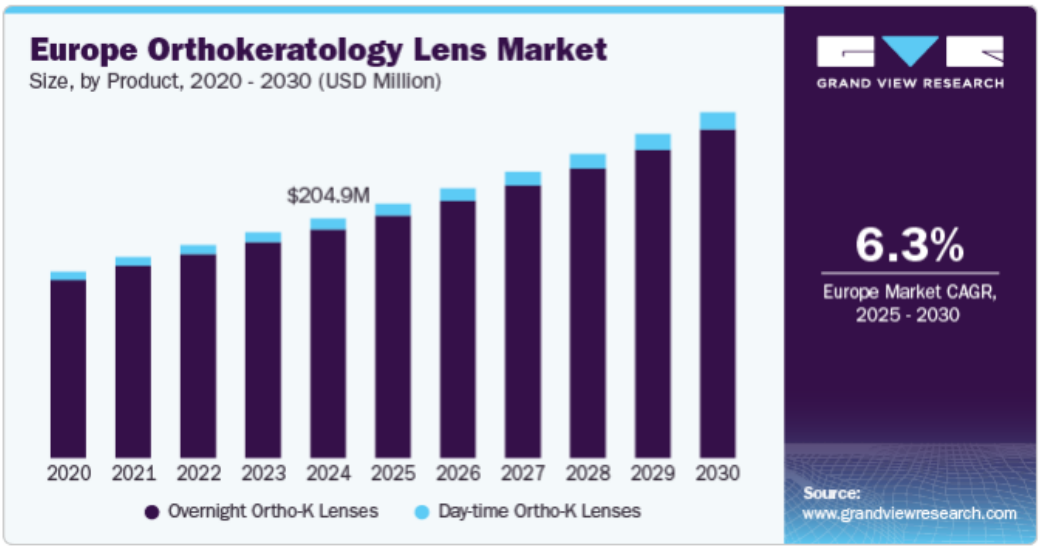

Figure 2. CAGR European orthokeratology lens market (*Size by Product, 2020-2030, Grand view research*)

Specifically, the **European orthokeratology lens market** was valued at **USD 204.9 million** in 2024 and is forecasted to reach roughly **USD 295.6 million** by 2030, growing at a CAGR of ~6.3%

Leading industry insights suggest the global market will expand from **USD 990.6 million in 2024** to as much as **USD 3.99 billion by 2032**, with a projected CAGR of around 19% during this period.

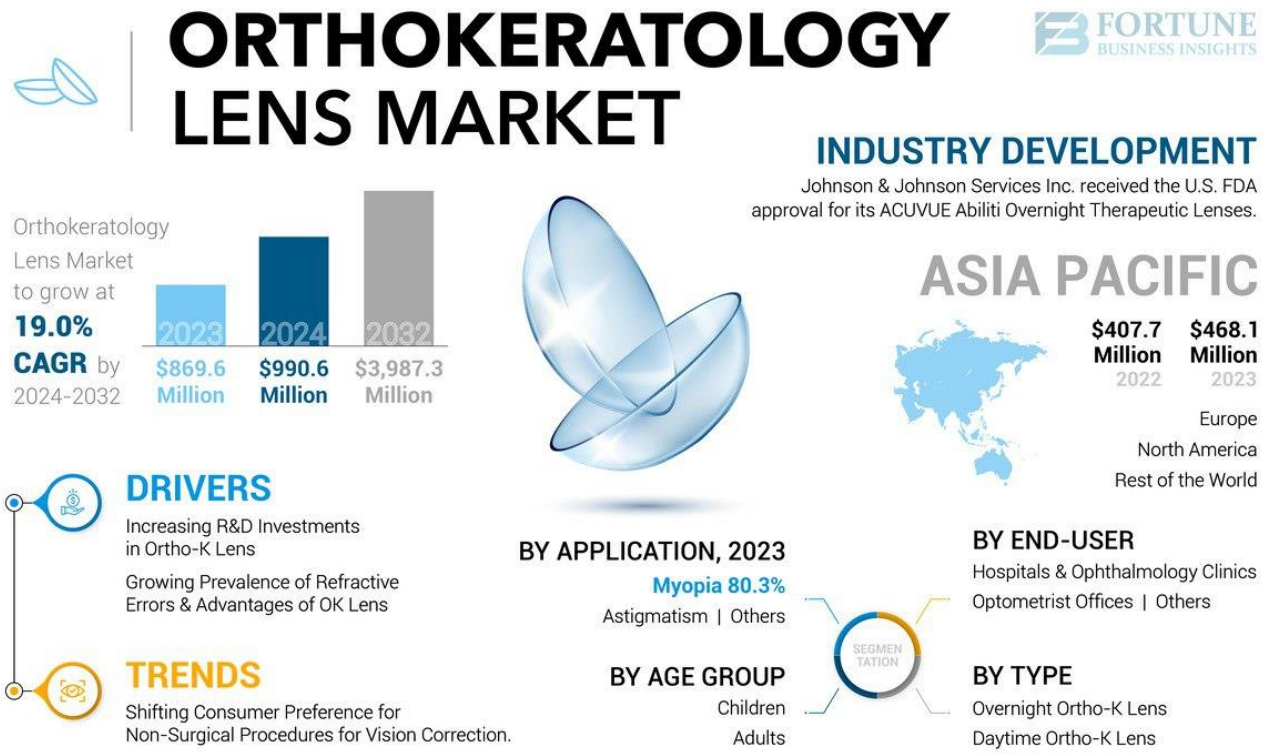

Figure 3: Global Ortho-K Lens Market Trends, 2023–2032 (*Forecased growth estimated by Fortune business insights*)

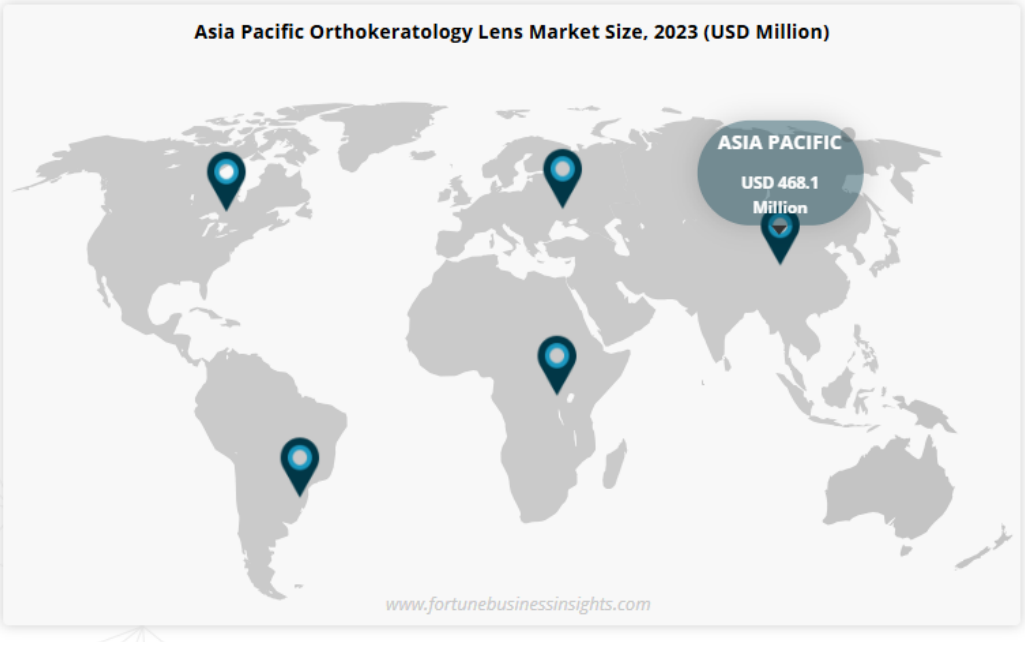

Figure 4. Regionally, the market is studied across Asia Pacific, Europe, North America, and the rest of the world *(Fortune business insights, orthokeratology lens market, 2024)*

Furthermore:

In South Korea–the leading exporter of Ortho‑K lenses–the domestic market size for myopia control spectacles and Ortho‑K lenses reached approximately USD 1.8 billion in 2024, with an expected CAGR around 10% thereafter.

This robust growth is mirrored by trade flows into the European Union. While exact EU import trade data was limited, the market trends and tariff-free framework of the EU–Korea Free Trade Agreement support continued growth in imports from South Korea to EU member states.

Discipline and compliance impact:

Several manufacturers–especially Korean exporters–faced heightened scrutiny under the EU Medical Device Regulation (MDR) in 2023, with new requirements around post-market monitoring, labeling accuracy, and conformity assessment leading to delayed registrations or recalls in some cases (such outcomes are consistent with WTO Technical Barriers to Trade concerns).

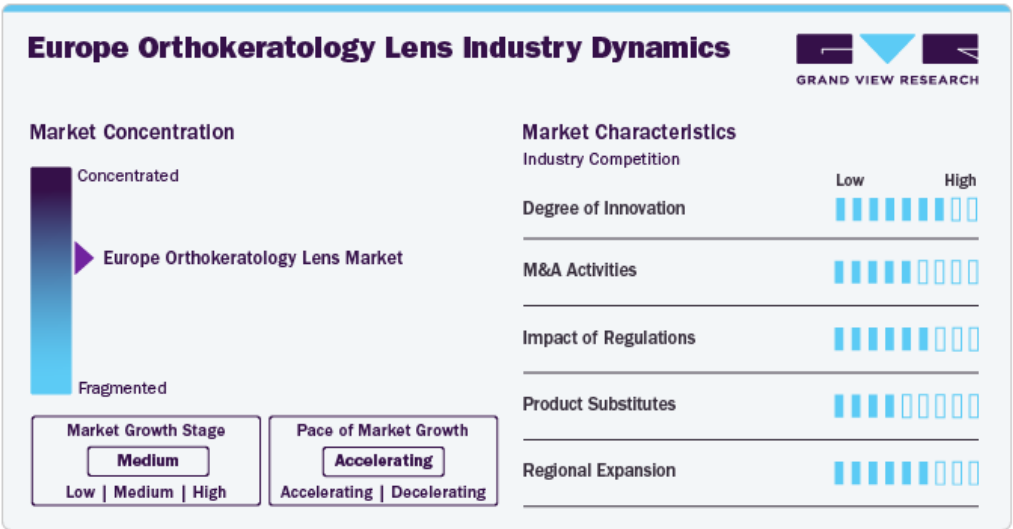

Figure 5. Market concentration *(Europe Orthokeratology Lens Industry Dynamics by Grand view research, 2020-2030)*

In 2021, the EU convened a panel under the TSD chapter of the EU–Korea FTA to address labor-rights violations, which set a precedent for trade-enforcement in high-value export sectors, including optical medical devices.

To summarize, we can conclude that the main findings in Orthokeratology Lens Industry are:

1. The Ortho-K lens market is experiencing rapid global growth–from ≈ USD 780 million in 2024, expanding to an anticipated USD 3–4 billion by early 2030s depending on sources (Fortune & others).
2. Europe represents a substantial and growing share (~USD 205 million in 2024), with strong regulatory frameworks and rising uptake in youth myopia care.
3. South Korean exports play a strategic role in meeting European import demand; domestic production reached ~USD 1.8 billion in 2024, bolstered by innovation leaders such as Lucid Korea.
4. Regulatory compliance under EU MDR and FTA-based labor standards remains a central trade discipline mechanism, with documented enforcement potential affecting market access in both product-safety and sustainable labour domains.

Technological innovation is a central force in the development of the global orthokeratology (Ortho-K) market. Advanced gas-permeable materials, AI-driven topography modeling, and 3D-printed lens molds have significantly improved the precision, safety, and customization of Ortho-K lenses. For instance, Lucid Korea and other leading manufacturers have begun integrating machine learning algorithms to optimize lens fit and corneal response predictions in pediatric patients. These systems analyze ocular biometrics in real time and adjust design parameters accordingly, thereby improving clinical outcomes and reducing fitting time (*Lucid Korea Brochure, 2024*).

In terms of sustainability and global policy alignment, Ortho-K lenses contribute indirectly to the United Nations Sustainable Development Goals (SDGs). Specifically: Goal 3 (Good Health and Well-being): by offering non-invasive, reversible alternatives to refractive surgery and helping to curb the global myopia epidemic. Goal 9 (Industry, Innovation and Infrastructure): through digital health

innovation and investment in high-tech medical manufacturing. Goal 12 (Responsible Consumption and Production): as single-lens nightwear usage reduces the need for disposable daytime contacts and eyeglasses. Goal 8 (Decent Work and Economic Growth): as the industry creates specialized, skilled jobs in biomedicine and optical design, especially in East Asia and the EU.

Governments worldwide are investing in regulatory infrastructure to support the growth of safe and standardized trade in medical devices like Ortho-K lenses. For example, South Korea's MFDS (Ministry of Food and Drug Safety) has streamlined export certification under GMP and ISO 13485 standards. The European Commission funds innovation under the EU4Health program and enforces strict post-market surveillance under MDR 2017/745. Ukraine has recently begun aligning national medical device registration with the EU's CE certification system, facilitating mutual recognition and faster import approvals *(Bazaluk O., 2022; Tsygankova T. 2022; Tananaiko T., 2023; Shlapak A., 2023; Shlapak A., 2023).*

In order to dynamize international trade in Ortho-K lenses, several logistical and policy frameworks must be improved. These include:

– Standardized electronic data exchange for lens prescriptions and biometric scans.
– Cross-border certification platforms that verify ISO, CE, and ILO compliance in real time.
– Trade facilitation mechanisms under WTO TBT and SPS agreements to ensure lens materials meet international safety codes.

Changes in public health policy are also influencing the regulatory environment for Ortho-K lenses:

School vision screening mandates in EU countries and East Asia are driving increased diagnosis and early correction of myopia.

Public-private partnerships are forming to subsidize corrective devices for children, increasing equitable access and expanding market reach.

Reimbursement reforms under national health insurance programs are slowly extending coverage to Ortho-K lenses in countries like Germany, the Netherlands, and Japan.

International standardization plays a crucial role in facilitating Ortho-K trade:

– Quality control: Compliance with ISO 14534, ISO 13485, and EN ISO 21987 ensures product performance and patient safety.
– Interoperability: Common standards help ensure Ortho-K lenses and diagnostic devices are compatible across countries, reducing regulatory duplication.
– Market development: Clear labeling, traceability, and conformity pathways reduce risks for investors and speed time-to-market for manufacturers.

The future of Ortho-K trade will depend on a country's ability to combine technological, regulatory, and logistical strengths. For example, South Korea has strong manufacturing capabilities and innovation but faces scrutiny over labor rights under EU FTAs. Europe offers a stable and lucrative market but maintains complex regulatory requirements that challenge new exporters. Emerging markets like Ukraine and Vietnam are expanding Ortho-K accessibility but still require external investment to upgrade certification systems and health infrastructure.

In conclusion, the prospects for international trade in Ortho-K lenses are promising but contingent on harmonized global regulations, sustainable innovation, ethical labor practices, and continued government investment in digital and health infrastructure. Much like hydrogen in the energy sector, Ortho-K lenses in healthcare represent both a commercial opportunity and a pathway to achieving long-term global development goals.

Conclusions. Thus, the international trade of orthokeratology (Ortho-K) lenses is poised for active growth and institutional support, particularly in the context of rising global demand for pediatric myopia control and non-invasive vision correction technologies. However, to achieve significant long-term success, the sector must overcome regulatory, technical, and ethical challenges. Theoretical and empirical studies, as well as recent market trends, confirm the high commercial and medical potential of Ortho-K lenses. Yet, barriers remain in the form of complex certification procedures, varying safety standards, and trade friction arising from labor rights and sustainability concerns.

International trade in Ortho-K lenses has already become an influential factor in shaping healthcare access and medical innovation, especially in highly regulated regions like the European

Union. The trade discipline observed through enforcement of CE certifications, EU MDR rules, and labor clauses in FTAs such as the EU-Korea agreement demonstrates how the lens sector is both a beneficiary and subject of evolving international trade governance. These regulatory shifts require significant adaptation from exporters, particularly in South Korea, where the majority of Ortho-K production is concentrated.

The future growth of Ortho-K trade will require systemic changes in both national and international policy:

Harmonization of medical device standards (ISO 14534, EN ISO 21987).

Transparent and digitally streamlined product traceability mechanisms.

Greater cooperation between regulatory bodies and manufacturers across jurisdictions.

Inclusion of sustainability and labor rights in the medical supply chain.

The integration of innovation, such as AI-based fitting systems and smart lens coatings, reinforces the need for updated classification systems and risk assessments within regulatory frameworks. As such, innovation must be met with parallel advancements in policy, funding, and infrastructure.

Despite persistent obstacles–including market fragmentation, certification bottlenecks, and import/export documentation delays–various national and supranational initiatives provide grounds for optimism. Countries such as South Korea, Germany, and Ukraine are either advancing lens production technology or aligning their regulations with global standards, while institutions like the WTO and European Commission continue refining trade facilitation tools.

Therefore, the Ortho-K lens sector faces a complex but promising path forward, involving trade diplomacy, technological modernization, and institutional development. With continued public-private investment, harmonized international standards, and stronger compliance mechanisms, the Ortho-K lens industry can secure its role not only as a key segment of the global medical devices market, but also as a contributor to health equity, sustainable development, and innovation-driven trade growth in the 21st century.

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